PREGNANCY OUTCOMES IN SANTA CLARA COUNTY 1980-1985

GEORGE DEUKMEJIAN
GOVERNOR
STATE OF CALIFORNIA

PREGNANCY OUTCOMES
IN
SANTA CLARA COUNTY
1980-1985

GEORGE DEUKMEJIAN
GOVERNOR
STATE OF CALIFORNIA

PREGNANCY OUTCOMES

IN

SANTA CLARA COUNTY

1980-1985

Epidemiological Studies and Surveillance Section
California Department of Health Services
2151 Berkeley Way
Berkeley, CA 94704

May 1988

Acknowledgements

These studies were conducted by the California Department of Health Services (CDHS) in collaboration with its contractor, the California Public Health Foundation. The research was carried out under the leadership of Shanna Swan, Ph.D, and Raymond Neutra, MD, DrPH.

The principal authors of this report were: Shanna Swan, Ph.D (Section 1), Margaret Wrensch, Ph.D (Section 2), Margaret Deane, MPH (Section 3), Gary Shaw, Ph.D (Section 4), and Kathleen Claxton, MA (Section 5).

The following CDHS and contract staff contributed in the areas indicated:

Data collection, analysis, and management: Luana Acton, John Andrew, Julie Brown, Martha Duncan, David Epstein, Laura Fenster, Peggy Hartsell, Alexandra Hunter, Warren Kennell, Robin Levinson, Pam Lindsey, Jane Lipscomb, Jorge Lizarraga, Lorraine Malcoe, Shelly Mandel, Carol Mattison, Carol McElheney, Kimberly Newton, Juan Perez, Csaba Polony, Theresa Ramirez, Dennis Shusterman, MD, Sharon Trammel, Kitty Tsui, Lorna Wallace, Soora Wi.

Administrative support: Jill Touloukian.

Editorial support: David Epstein.

Clerical support: Dolce Brookman, Susan Freeman, Julie Lammers.

Technical Consultants to the Santa Clara County Pregnancy Outcome Studies were: Delia Alvarez, Stephen Coray, MD, Louise Detwiler, David Erickson, MD, Brenda Eskenazi, Ph.D, Bernice Giansiracusa, MD, Nancy Hicks, Robert Morgan, MD, Henry Ongerth, Beverly Paigen, Ph.D, Diana Petitti, MD, MPH, Arthur Reingold, MD, Kenneth Rothman, DDS, DrPH, Steve Samuels, Ph.D, Nicholas Toth, MD, Donald Wharton, MD.

Assistance and data were also provided by the Santa Clara County Health Department, the Great Oaks Water Company, the Fairchild Camera Company, and by International Business Machines Corporation.

Without the assistance of the individuals, companies, and agencies mentioned, and the cooperation of the families that participated, their physicians, and the medical records staffs of Santa Clara County hospitals, these studies would not have been possible.

TABLE OF CONTENTS

Table Titles

Pregnancy Outcome Follow-up Study: Pregnancy Outcomes in Four Census Tracts of Santa Clara County 1980-1985

Figure Titles

Overview Across Studies

1. Overview Across Studies

Introduction

This report presents the results of two epidemiological studies of pregnancy outcomes and two related exposure assessments. These were conducted by the Epidemiological Studies and Surveillance Section of the California Department of Health Services (CDHS) with the cooperation of its contractor, the California Public Health Foundation, and the Santa Clara County Health Department. These studies were conducted to follow-up on two studies released by CDHS in January, 1985 (1).

In the previously released studies the Department reported a doubled rate of spontaneous abortions and tripled rate of birth defects in women who resided in a census tract (Los Paseos) which received drinking water from a well which had been contaminated by leakage of solvents from an underground storage tank operated by the Fairchild Semiconductor Company in South San Jose. At the same time, the Department documented a 2.6-fold increased rate of major cardiac malformations among the children of women residing in the seven-census tract area through which the contaminated water was distributed. The first of these studies ruled out confounding as the cause of these findings, and for both the role of the leak in causing these excesses was uncertain. Therefore, the Department conducted two epidemiological studies and two exposure assessments to followup on these results.

The first study in this report, the Pregnancy Outcome Follow-up Study (POFS), is similar in design to the first interview study. However, in POFS, women in a census tract adjacent to Los Paseos, which was thought to also have been exposed to water from the contaminated well, were interviewed about their pregnancies in 1980-81, in addition to re-interviewing the women in Los Paseos. Furthermore, this study looked at pregnancies in 1982-85 as well, so that the effect of closing the contaminated well could be analyzed. In a companion report on water exposure and pregnancy outcome released concurrently by the Department, this study is referred to as Fairchild II.

The second part of the POFS study, Comparison of Original and Follow-up Fairchild Study Populations, compares women interviewed in both the first Fairchild study and in POFS with those who were not reinterviewed.

The 1985 Cardiac study was based on hospital data only and no interviews were conducted. In the Cardiac Study: Follow-up Cluster Investigation, cases and normal controls were interviewed in order to obtain more detailed information on exposure to water, to rule out confounding as an explanation for the observed association, and to look at the prevalence of cardiac defects in more recent births.

The 1985 studies contained limited information about the level and extent of the water contamination. In order to obtain more precise exposure information, hydrogeologic modelling of water flow within the distribution system of the water company which had operated the contaminated well was conducted. This is the subject of The Great Oaks Water Distribution Study, presented separately (2).

Following the discovery of the leak, the Fairchild company prepared a materials balance report at the request of the Regional Water Quality Control Board. This report indicated no appreciable leakage from the failed tank before late May 1980. Because of the importance of the timing of the leak in interpreting the excesses documented in the epidemiological studies, the Department conducted a reanalysis of the Fairchild report. This Material Mass Balance Analysis is contained in this report.

These studies reflect an unusually complete effort on the part of the Department to investigate the causal relationship between the clusters of adverse pregnancy outcomes documented in 1985 and the contamination episode. They represent three years of work, cooperation of 10,000 households and interviews with 1,500 women and have been extensively reviewed by nationally recognized scientists with expertise in these areas. The Department feels that these studies, in conjunction with the studies released in January 1985, address the "Fairchild question" as completely as is scientifically possible. This Section summarizes each of the component studies.

PREGNANCY OUTCOME FOLLOW-UP STUDY

Background and Methods

In late 1981, residents of the Los Paseos neighborhood in South San Jose noticed a possible excess of spontaneous abortions and birth defects in their neighborhood. Report of this concern was received by the Santa Clara County Health Department following the announcement of the leak of toxic chemicals from an underground waste solvent storage tank operated by the Fairchild Semiconductor Company. Contaminants from this leak were measured in the drinking water of a well (Well #13) serving this community. A number of chemicals were measured; a high level of the solvent 1,1,1-trichloroethane (TCA) was of particular concern. Despite the fact that no human or animal studies conducted up until that time suggested adverse reproductive effects of the chemicals which had been identified, the California Department of Health Services, in cooperation with the Santa Clara County Health Department, decided to conduct two epidemiological studies to address this problem.

One of these, an interview study of women who had been pregnant in 1980-81 while living in either the concerned community (Los Paseos) or a demographically similar control tract, had the following objectives: (1) to determine whether a cluster of spontaneous abortions and congenital malformations had actually occurred, (2) to determine whether any maternal risk factors could account for this cluster and (3) to determine whether the cluster was related to the leak of chemicals into Well #13. This study found that (1) spontaneous abortions and malformations had occurred above the expected rates, (2) maternal risk factors could not explain these excesses and (3) the evidence was insufficient to determine whether the leak of chemicals into Well #13 caused the excess. The Pregnancy Outcome Follow-up Study was then undertaken to address this last, unanswered question.

The Pregnancy Outcome Follow-up Study (POFS) had the following objectives: (1) to determine whether the high rates seen in Los Paseos in 1980-81 persisted in 1982-85, after the well with known contamination was closed and (2) to study rates in a tract adjacent to Los Paseos, in which Well #13 was

located, to see whether rates were high there in 1980-81. For this purpose a second unexposed tract was selected for comparison. Rates in the two new tracts were also compared for pregnancies in 1982-85. A map showing the study areas is included (Figure 1.1). A schematic representation of the study design is shown in Figure 1.2. This study also utilized results of hydrogeologic modelling (Great Oaks Water Company Distribution Study) to estimate the exposure to water from Well #13 and to TCA for each study pregnancy.

A household enumeration was conducted in the four study areas in order to identify women who had been pregnant in 1980-85. Subsequently, women identified through the enumeration as having been pregnant were interviewed about each eligible pregnancy, those for which the woman resided in the study area throughout the pregnancy. These interviews included a complete pregnancy history and detailed information on exposure to water as well as demographics and potential confounders such as parent's occupation and industry, chemicals, medications, smoking, alcohol and caffeine. All spontaneous abortions included in the analysis were validated through medical record review or physician interview. Spontaneous abortion analyses were based on one pregnancy per woman. Birth defects included in the analysis were categorized as "reportable" by the California Birth Defects Monitoring Program (CBDMP) and validated by medical chart review. Birth weight analyses were also conducted, using birth weight as recorded on the birth certificate.

Results

Enumeration was completed in 10,063 households (91.6%) and identified 2,713 women who had been pregnant, of whom 95% were interviewed. Of these, 1376 pregnancies were eligible for further study. A total of 181 spontaneous abortions were validated. After selecting one pregnancy per woman, 103 spontaneous abortions were available for analysis. (This selection decreased the spontaneous abortion rate from 13.2% to 9.9% but did not affect the study's conclusions with respect to year or census tract.)

The rate of spontaneous abortion in the new exposed area in 1980-81 was 4.7%, considerably lower than the overall rate. Thus, there was no evidence that this area was at higher risk than expected before the contaminated well was closed. It is interesting to note that the odds ratio for comparing Los Paseos to its control tract in 1980-81 (OR=3.5) was similar to that seen in the original study (OR=2.4). No elevation in rates was seen after 1982 for either the exposed areas (10.8%) or the control areas (10.6%). Odds ratios comparing exposed and control tracts are shown in Figure 1.3.

A large number of potential risk factors were analyzed, and a number of risk factors for spontaneous abortion were identified including: maternal age less than 20 or over 35, multiple prior fetal loss, and alcohol use of four or more drinks per week. All of these risk factors have been previously reported in the literature. Adjusting for these and other variables did not alter the results on study area or year.

A total of 37 validated birth defects were considered reportable by CBDMP. As in the prior study, an unusually high prevalence of birth defects (10.4%) was seen in the original exposed tract for 1980-81, but the prevalence in the new exposed tract was unusually low during the same time period (1.9%). After 1982, the frequency of birth defects in the exposed and control areas were similar (2.9% and 1.9%) and consistent with the prevalence reported by CBDMP for the five Bay Area counties (2.5%). Odds ratios for reportable birth defects are shown in Figure 1.4 by study year.

The frequency of low birth weight was also examined. The original study had reported a significant absence of low birth weight babies in the exposed area. In this study there was little difference seen between exposed and control areas in 1980-81 (2.4% and 2.6%) or during 1982-85 (3.8% and 4.0%). These results on low birth weight are summarized in Figure 1.5.

Hydrogeologic modelling was conducted to estimate the flow of water from Well #13 throughout the Great Oaks Water Company distribution system and the levels of TCA women were likely to have received during their pregnancy based on their address and dates. Modelling was not carried out for 1980 pregnancies because the engineer who conducted this analysis concluded that

it was unlikely that any homes received any significant exposure to TCA before January 1981. This study finds that the new exposed tract had a considerably higher likelihood of exposure to water from Well #13 during 1981 (60%-100%) than the Los Paseos area (20%-60%) (Figure 1.7). Thus, the low spontaneous abortion rate in the new exposed tract in 1981 is inconsistent with the assumption that water from Well #13 was associated with high rates.

Using the address reported on interview and the estimated TCA exposure at that address during the first month of pregnancy, it was possible to construct an exposure measure for each pregnancy. If the contaminated water from Well #13 had been responsible for the cluster of adverse outcomes in 1980-81, one would expect to see a higher TCA score for women with spontaneous abortions and birth defects than for those with normal live births. This was not the case. Mean estimated levels of TCA in these three groups are similar with the highest level of TCA associated with normal live births. This is shown in Figure 1.6.

In summary, there is no evidence from these data that rates of adverse pregnancy outcomes were elevated in the new exposed tract during 1980-81. If anything, there was an absence of adverse outcomes. Since hydrogeologic modelling shows that this new tract was more likely to have received contamination from Well #13 than the Los Paseos area, which was originally studied, the leak is a very unlikely explanation for the cluster of adverse outcomes seen in Los Paseos in 1980-81. This study also demonstrates that recent rates in both exposed and control areas agree with expected rates for adverse pregnancy outcomes.

COMPARISON OF ORIGINAL AND FOLLOW-UP FAIRCHILD STUDY POPULATIONS

Two of the census tracts in POFS had been examined three years earlier during the first interview study. This provided the opportunity to compare women interviewed in both studies to women who were in the first study, but not in the second because presumably they had moved away. In both the exposed and control census tracts, higher rates of SAB were found among

women who had apparently moved away than among women who still lived in the two areas (exposed tract: 24.4% vs. 19.3%, control tract: 15.7% vs. 7.9%). However, the odds ratios comparing exposed and unexposed tracts were similar among these two groups.

CARDIAC STUDY: FOLLOW-UP CLUSTER INVESTIGATION

Severe cardiac defects were among the adverse reproductive outcomes reported by residents of the Los Paseos area. These defects occur infrequently (about 3 in 1000 live births) and the interview study did not have enough births to determine whether an unusual number of these rare outcomes had occurred. Therefore, the Department conducted a second study in which hospital records throughout Santa Clara County were reviewed in order to identify cardiac defect cases among births in 1981 and 1982. Analysis was then carried out for the time period during which births were potentially exposed (January 1981 though September 1982). This study (1), released in 1985, documented that there were two cases in Los Paseos, which is more than expected. It also examined defects among births to women living in the seven census tracts receiving water from the Great Oaks Water Company which operated Well #13. This study found ten cardiac anomalies among women living in the seven census tracts when only four would be expected based on the prevalence in the remainder of the county (2.9 per 1000).

This original study was based on hospital records and addresses at birth only and no interviews were conducted. Therefore, women who drank only bottled water, or who moved to the seven census tract area shortly before giving birth would have been mistakenly counted as exposed. Furthermore, there were insufficient data to determine whether the prevalence of these defects returned to normal after Well #13 was closed. Therefore, the Cardiac Follow-up Cluster Investigation was undertaken.

A decision was made to interview all cardiac cases born in 1981-83, as well as a random sample of normal live births, in order to study the time period after the well was closed and to obtain more detailed information about exposure and possible confounders.

The California Birth Defects Monitoring Program (CBDMP) ascertained cases of congenital cardiac anomalies through a review of medical records at each of the eleven hospitals in Santa Clara County, as well as at the California Children's Service and one out-of-county referral hospital. Cases used for analysis were those for which a major cardiac defect had been diagnosed by one year of age among births in 1981-83.

The entire seven census tract area served by the Great Oaks Water Company was considered potentially exposed to contaminated water. Hydrogeologic modelling was later used to identify areas most likely to receive this water. The onset of the exposure period remained uncertain. However, the end of the exposure period is known; Well #13 was removed from service on December 7, 1981. Allowing one week for residual contamination in the distribution system and considering the first seven weeks after conception to be the period during which exposures are most likely to affect the fetal heart, it is estimated that births after September 6, 1982 are unlikely to have had exposures relevant to these defects. Therefore, births which occurred in January 1, 1981-September 6, 1982 are considered potentially exposed if the mother lived in the seven-census tract area.

The analysis was conducted in two parts. Children born between September 1, 1982 and December 31, 1983 were considered unexposed and analyzed separately. Prevalence rates were calculated for this time period but mothers of these children were not interviewed. On the other hand an attempt was made to locate and interview the mothers of all cases born in the study period throughout Santa Clara County. An equal number of live born controls were selected at random from birth certificates throughout the county and interviewed as well. Mothers were interviewed concerning their water exposure through consumption and showering and bathing, at home, work and other places regularly visited. The interview also included information on alcohol consumption, education, employment, smoking, diabetes, epilepsy and family history of cardiac disease.

Using the hydrogeologic modelling presented in the Great Oaks Water Distribution Study, each case and control with first trimester residence in the Great Oaks Water Company service area during the study period was

assigned a score, reflecting exposure to TCA via Well #13 water during the first trimester.

Results

During the comparison time period (9/1/82-12/31/83) there were three cases born in the study area, which was slightly less than expected. In this area the prevalence was 1.7 per 1000 compared to 3.2 in the remainder of the county. These data have been presented separately (3).

Overall, 106 mothers of cases born in the study period (78.3%) and 114 control mothers (84.2%) were interviewed. After correcting for address (when the first trimester address assigned a different exposure than the birth address) or water use (when woman drank no tap water), the odds ratio was very similar to that seen in the original study; the original study had presented a relative risk of 2.2, while this follow-up study found an odds ratio of 2.3 after these adjustments for misclassification. The estimate from the first cardiac study did reach traditional levels of statistical significance (95% CI, 1.2, 3.9) although the 95% confidence interval for this follow-up study included 1.0 (95% CI, 0.61, 8.4). Adjustment for potential confounders had little effect on these estimates.

Of the interviewed cases and controls, only six cases and four controls could be assigned an exposure score. This is because all other study subjects had first trimester residence before January 1981 or outside the study area. Of the six cases for whom scores could be assigned, only two lived in the study area, the remaining four visited frequently. For controls, one visited the area and three lived there. Therefore, numbers were too small to determine the relative exposure of cases and controls and an additional random sample of normal controls was selected. Exposure scores were based on census tract of residence at birth, since the additional controls were not interviewed. The mean score for cases suggested a somewhat higher likelihood of exposure than among controls, but the difference did not approach statistical significance.

This study also examined the temporal distribution of cases throughout the study period. From the beginning of 1982 until the end of the study period (September 1982), seven cases would be expected, if the excess prevalence seen in 1981 in the study area continued at the same level until the well was closed. However, only two cases were seen. These cases were born in April, 1982, and none were born in the study area after that time until after September 1982. This deficit of cases, compared to the expected excess in January-September 1982 is statistically significant ($p=.03$).

Discussion

Although the prevalence of cardiac defects returned to normal after the study period, this drop did not coincide with the closing of Well #13. There was a significant deficit of cardiac cases in the study area during 1982, when seven would have been expected, had the elevated prevalence seen in 1981 continued. This evidence makes the leak an unlikely explanation for the cluster in 1981. While interview data provided information with which to reclassify a number of subjects with respect to exposure, the effect measure changed little after these adjustments. The exposure scores which could be assigned to the few cases in the study area and study period were slightly higher on average than that for controls, but of these cases, only two lived in the study area. Therefore, though this information suggests slightly higher exposure of cases that controls within the study area, it is based on extremely small numbers.

On balance, it appears unlikely that the excess of cardiac defects seen in 1981 was due to waterborne exposure to TCA from Well #13, although it probably will never be possible to determine conclusively what role the leak played in this observed cluster. However, CBDMP is conducting ongoing surveillance of these and other birth defects and will continue to investigate clusters related to water or other exposures.

GREAT OAKS WATER DISTRIBUTION STUDY

Background and Methods

The 1985 Pregnancy Outcome Study made the assumption that all women residing in the Los Paseos area in 1980-81 were equally likely to have been exposed to contaminated water from the Fairchild leak. This assumption was made for simplicity and because no other data were available. Two pieces of information were missing. The first concerns the timing and extent of the leak. When did it start and how rapidly did the concentration of chemicals increase in the contaminated well? These are difficult questions to answer, because no water testing for these chemicals was done in that area prior to December 1981. The second question concerns the distribution of water within the service area of the Great Oaks Water Company. The Great Oaks Water Distribution Study was conducted in an attempt to answer these questions.

The Great Oaks Water Distribution Study uses computerized hydrogeologic methods to model the distribution of water flow within the system. Input to this model are: the Great Oaks Water Company pipe network, well elevations, pumping records for each well and records from meters to establish user demand. Using these data the proportion of water from Well #13 at each of 124 nodes, or small areas, within the system, was estimated. These estimates are independent of any assumptions about the amount of TCA in the system.

The timing of the initial leak, and the rate at which TCA increased at Well #13, was estimated using several alternative models.

Results

The Water Distribution Study showed that the distribution of water from Well #13 was very non-uniform across the seven census tracts that make up the Great Oaks Water Company service area. The distribution patterns changed somewhat from month to month, but not a great deal. Similarly there was little variation across nodes within a census tract. Ranges of the mean proportion of water from Well #13 received in each census tract are shown in

Figure 1.7. As can be seen, the census tract originally considered exposed to Well #13 (Los Paseos) was less exposed than the adjacent tract which was considered as the new exposed area in POFS. The results on the timing of the leak are less certain, but none of the scenarios considered would predict that the contamination reached Well #13 in any appreciable amounts before January of 1981.

MATERIAL MASS BALANCE ANALYSIS

Backgrounds and Methods

A materials balance analysis is commonly used in engineering studies to assess the inflow and outflow of materials within a system. Such an analysis can be used to estimate the amount of material lost, for example, through a leak. Such an analysis was conducted by the Fairchild Corporation in the spring of 1982 at the request of the Regional Water Quality Control Board. This report indicated no appreciable leakage before May 1980. Because the timing of the leak was important for interpreting the epidemiological studies, the Department decided to reconstruct the Fairchild analysis. With the cooperation of the Fairchild company and local agencies, a large number of documents were reviewed for this purpose. Due to limitations in the available data and in resources available for this task, the Department was only able to partially reconstruct the original analysis.

Results

The Materials Balance Analysis did not identify sufficient documentation to provide an accurate estimate of the onset of the underground tank leak at Fairchild. Nevertheless, the review did not identify any data which would appreciably alter the estimate of May 1980 which was contained in the original Materials Balance Report. An initial leak at this time would be consistent with the estimates obtained in the Great Oaks Water Distribution Study for when contamination reached Well #13. The Department found that the components used to solve the imbalance equation, such as solvents

purchased, evaporated or hauled, must be considered unreliable and the extent of solvents lost remains uncertain.

DISCUSSION

These studies represent an unprecedented effort on the part of the CDHS to conduct a cluster investigation. Together with the original Fairchild studies released in January 1985, they have required six years and over one million dollars to conduct. They have also required the patience and participation of the citizens of four census tracts who have cooperated during these years. The weight of the evidence is against the leak from the Fairchild plant as a cause of the original cluster. Nevertheless, there is little doubt that a cluster did occur, and its cause will probably never be known with certainty. Continued work by the Department on prenatal exposures may shed light on causes of this and other such frequently occurring clusters in the future.

<u>References</u>

1. Epidemiological Studies Section, California Department of Health Services: Pregancy Outcomes in Santa Clara County, 1980-1982. Reports of Two Epidemiological Studies, California State Publications Section. Reports 7540-958-1301-5, 1985.

2. Murphy, P: The Great Oaks Water Distribution Study, 1988.

3. Swan SH, Shaw G, Harris J, Neutra RR: Congenital cardiac anomalies in relation to water contamination. Santa Clara County, California 1981-83; submitted for publication to Amer J Epid, 1988.

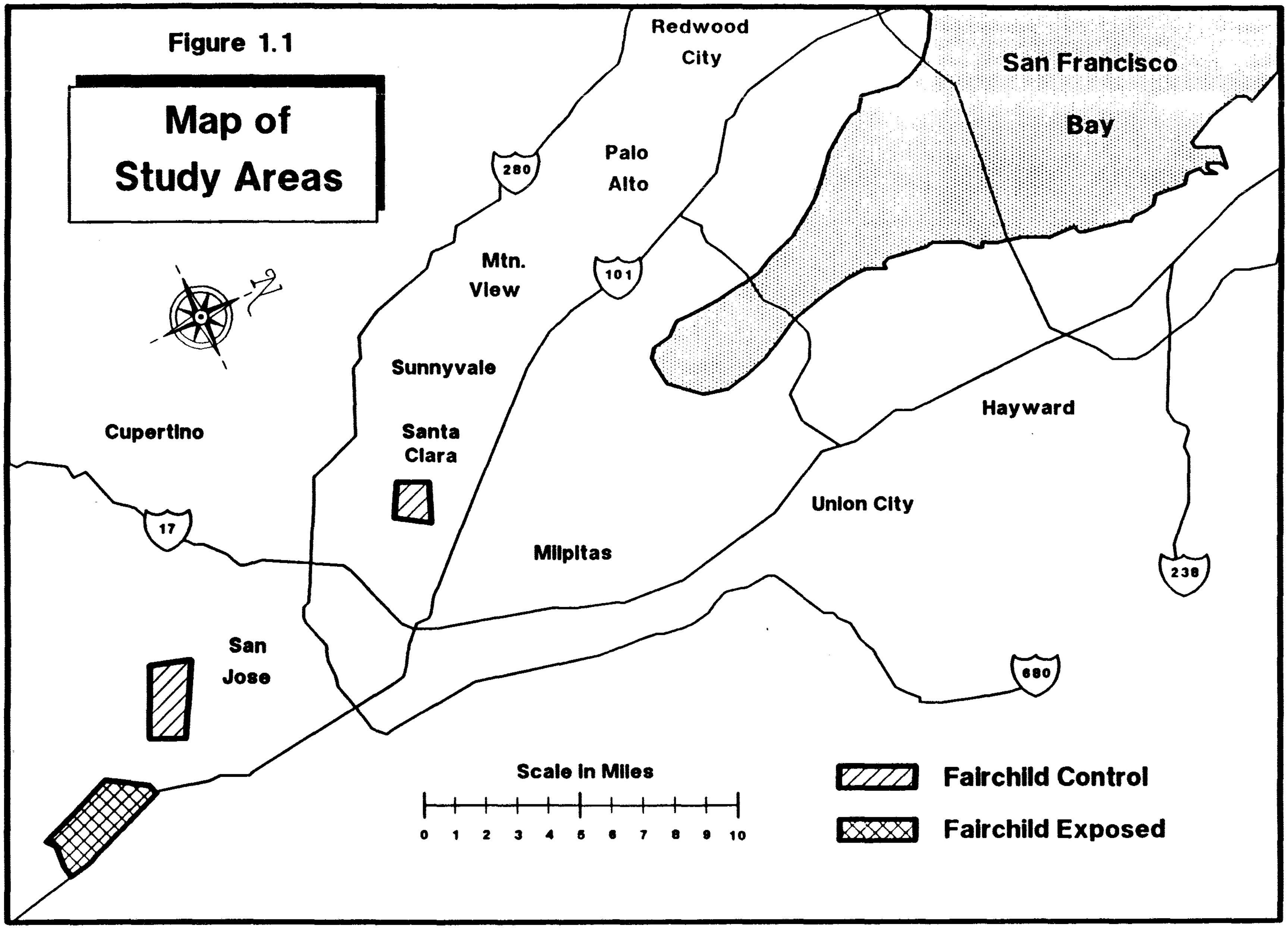


Figure 1.1
Map of Study Areas
Redwood City
San Francisco Bay
Palo Alto
280
Mtn. View
101
Sunnyvale
Cupertino
Santa Clara
17
Milpitas
Union City
Hayward
238
San Jose
680
Scale in Miles
0 1 2 3 4 5 6 7 8 9 10
Fairchild Control
Fairchild Exposed

Figure 1.2 Four Census Tracts in Santa Clara County 1980 - 1985

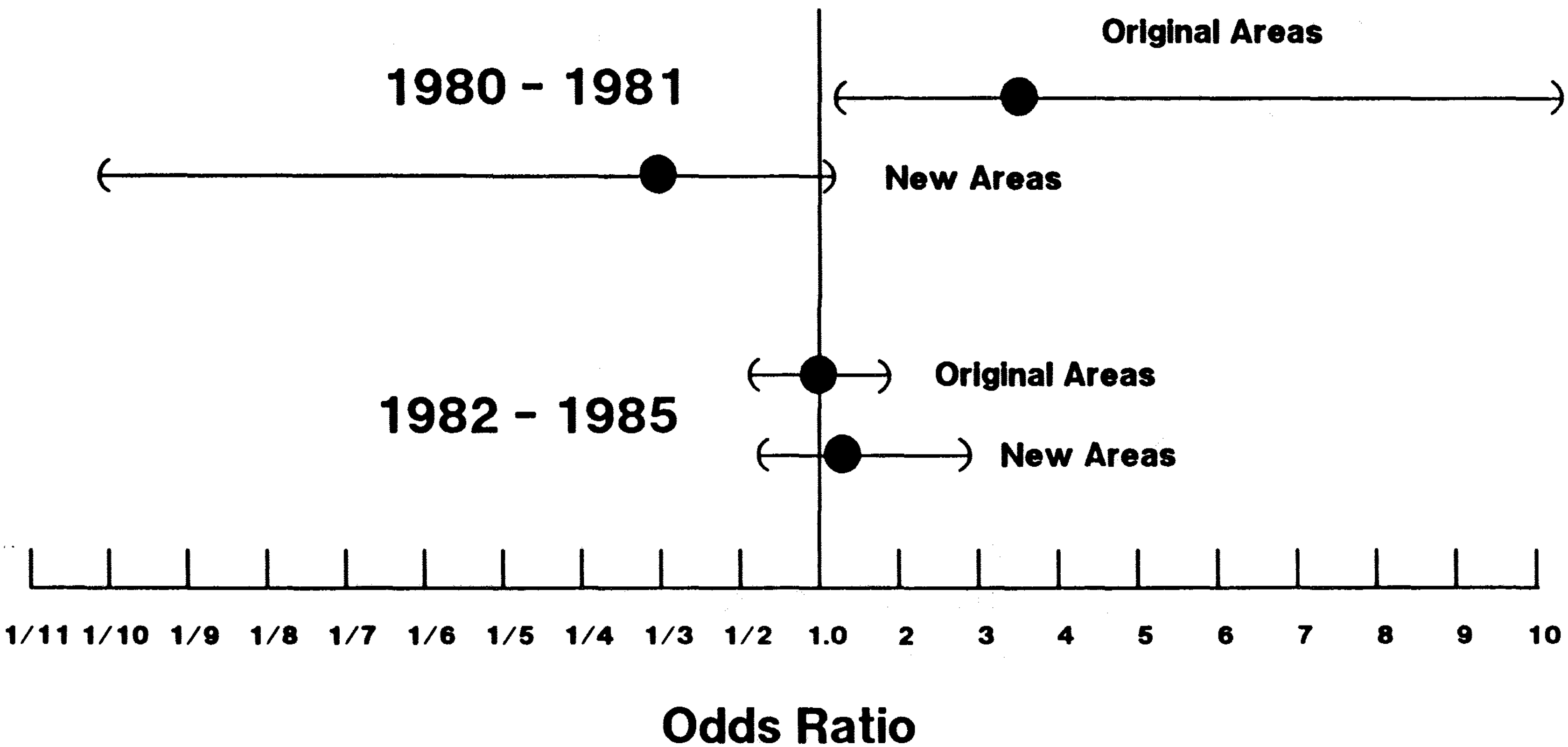
Census Tracts

	Original Study Area 5120.12	New Study Area 5120.11	Original Study Area 5120.08	New Study Area 5053.0204
1980 - 1981	Exposed*		Unexposed	
Dec. 1981 Contaminated Well Closed				
1982 - 1985	Unexposed			

* Exposure to water contaminated by a leaking chemical waste tank at the Fairchild Camera Company.

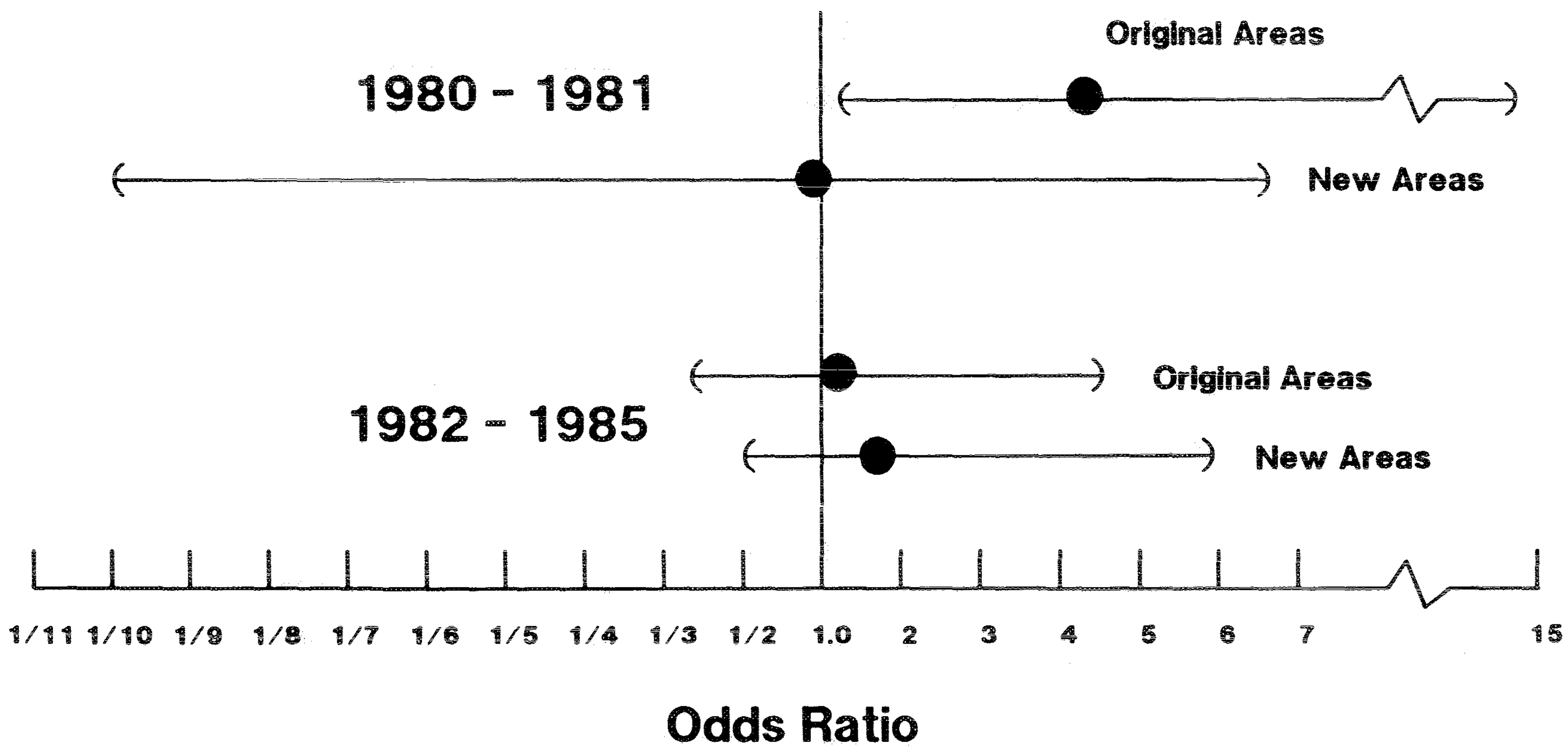
Pregnancy Outcome Follow-Up Study

Figure 1.3 Odds Ratios and 95% Confidence Intervals for Spontaneous Abortions in Exposed vs. Unexposed Areas For 1980 - 1981 and 1982 - 1985



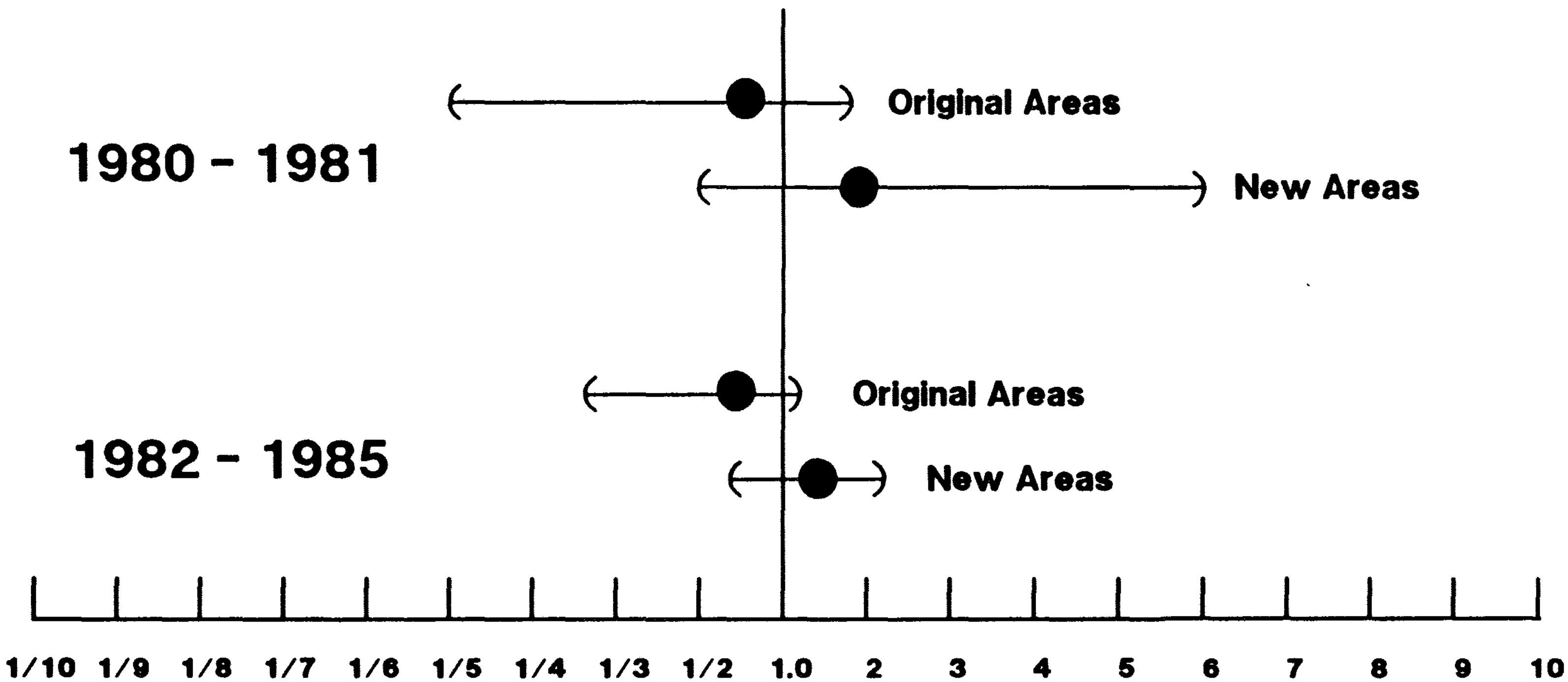
Pregnancy Outcome Follow-Up Study

Figure 1.4 Odds Ratios and 95% Confidence Intervals for Congenital Malformations in Exposed vs. Unexposed Areas For 1980 - 1981 and 1982 - 1985



Pregnancy Outcome Follow-Up Study

Figure 1.5 Odds Ratios and 95% Confidence Intervals for Low Birth Weight in Exposed vs. Unexposed Areas *
For 1980 - 1981 and 1982 - 1985



Odds Ratio

* All certificated births

Figure 1.6 Estimated TCA Exposure During 1st Month Of Pregnancy by Pregnancy Outcome

Original and New Exposed Areas Combined (1981)

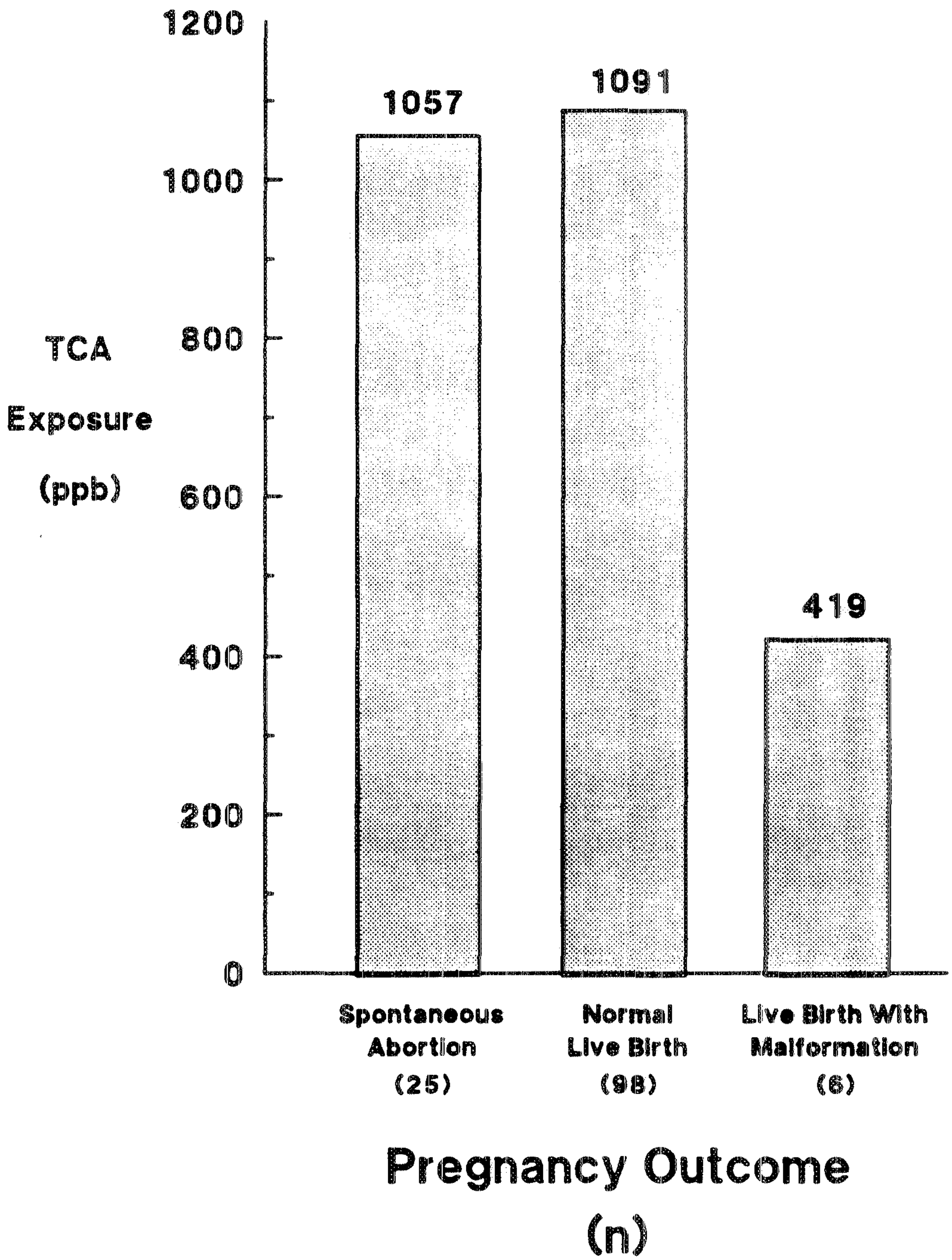
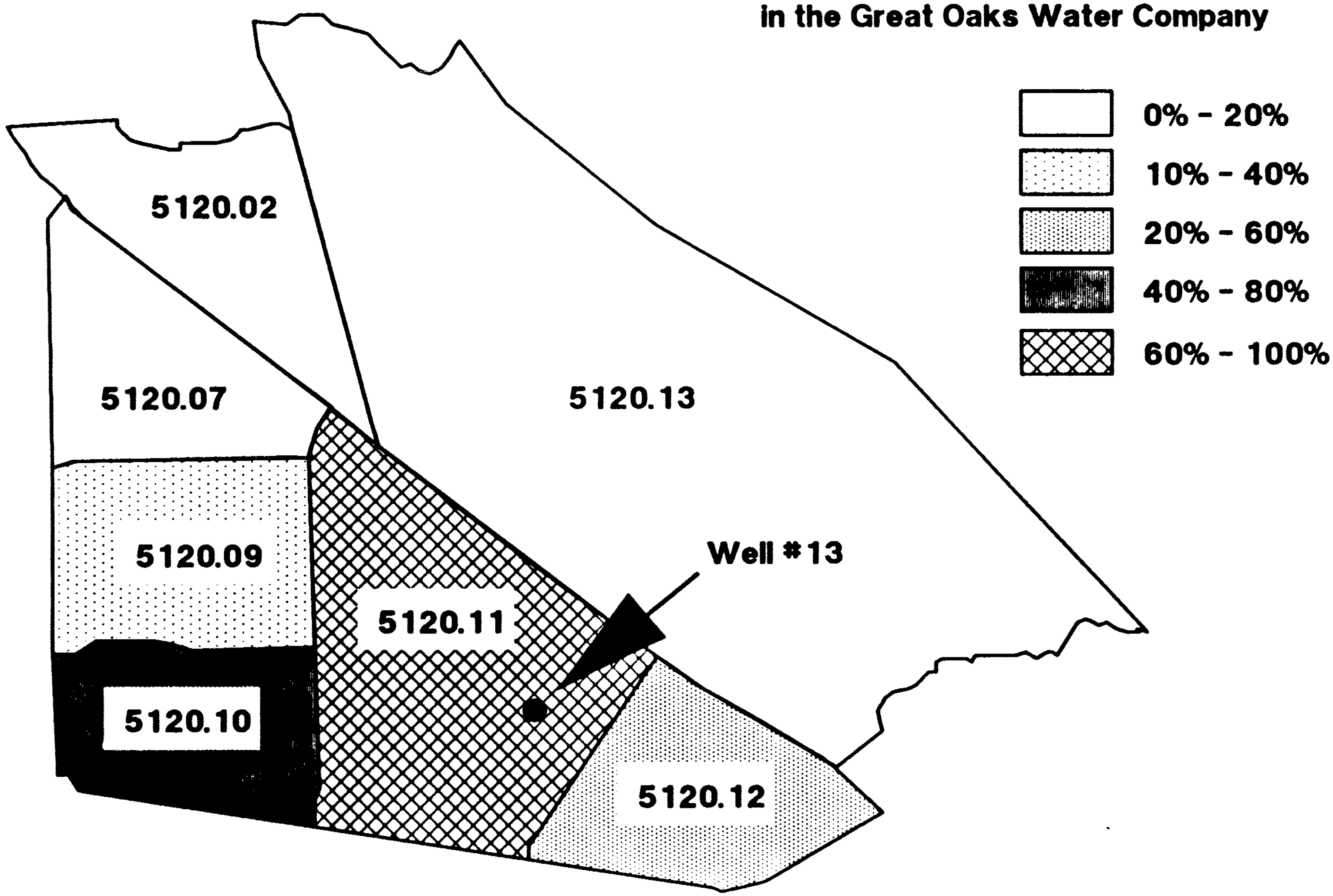


Figure 1.7

Estimated Percent of Water from Well #13 in 1981 for Census Tracts in the Great Oaks Water Company



2. Pregnancy Outcome Follow-up Study: Pregnancy Outcomes in Four Census Tracts of Santa Clara County 1980-1985

INTRODUCTION

Background

Two studies released in 1985 by the California Department of Health Services (CDHS) in cooperation with Santa Clara County (SCC) Health Department documented a significant excess of spontaneous abortions and birth defects in an area of the county served by the Great Oaks Water Company (GOWC) (1). These investigations were initially conducted because the community was concerned about a possible association between adverse reproductive outcomes and a leak of toxic waste into the community's water supply from the Fairchild Camera Company. In December of 1981, 1,1,1-trichloroethane (TCA) was measured in one GOWC well (Well #13) at 1,700 parts per billion, a level 8.5 times higher than the current California state action level. TCA also was detected at GOWC Well #8, but at levels below the standard. Other organic solvents, primarily 1,1-dichloroethylene (DCE), were detected at low levels in both wells.

This study is an extension of one of the previous investigations, the interview study of pregnancy outcomes in relation to water contamination in 1980-81 in San Jose, California (1). The original study examined adverse pregnancy outcomes including spontaneous abortions (SABs), birth defects, and low birth weight occurring among 1980 and 1981 pregnancies in two census

tracts. One tract (5120.12) was served by the GOWC and presumably received water from Well #13 that was contaminated with TCA and DCE. This tract is also known as the Los Paseos area. The comparison census tract (5120.08) was demographically similar to Los Paseos and was not served by GOWC. In 1982 the drinking water of the comparison tract was found to be free of contamination.

The original study showed: (1) that spontaneous abortions and congenital anomalies in the Los Paseos area occurred more frequently than in the control area; (2) the excess could not be attributed to differences in known maternal risk factors between the two areas; and (3) the indirect evidence regarding the extent and timing of exposure to contaminated water within the Los Paseos area was insufficient to determine whether the contaminated water of Well #13 of the GOWC caused the excess.

Rationale

This current study is designed to clarify and resolve questions raised by the original study. In particular, adverse pregnancy outcomes in the Los Paseos area (5120.12) and control area (5120.08) are compared for the period 1982 to 1985. Because the contaminated well was closed in December of 1981 and because only trace levels of contaminants were detected in other GOWC wells between 1982 and 1985, persistence of the excess of spontaneous abortions and birth defects into 1982 to 1985 would suggest that it was unlikely that the excess identified in the first study was due to exposure to the contaminated water. The current study also compares adverse pregnancy outcomes occurring in 1980-85 in another census tract served by GOWC (5120.11) to a comparable area not served by GOWC. Prior to the

hydrogeologic exposure analysis reported in the Great Oaks Water Distribution Study (GOWDS) (2), we assumed that residents of tract 5120.11 and 5120.12 were equally likely to have been exposed to water from Well #13 and to toxic chemicals leaked from Fairchild. The hydrogeologic analysis (2) indicated that residents of 5120.11 were actually more likely to have been exposed to water from Well #13 than residents of 5120.12. If the leak was responsible for the the adverse pregnancy outcomes in 5120.12, we would expect to see a similar or greater rate of adverse pregnancy outcomes in 5120.11 during 1980-1981 than in the Los Paseos area. Similarly this area (5120.11) should show elevated relative risk estimates compared to an unexposed but otherwise comparable tract.

STUDY OBJECTIVES

The present study had the following objectives:

1. To determine if the elevated rates of spontaneous abortions and birth defects in 1980-81 observed in the previously studied census tract (5120.12) persisted during 1982-85, after the well with known contamination was closed.

2. To determine the rates of adverse pregnancy outcomes (spontaneous abortions, birth defects and low birth weight babies) in a census tract (5120.11) which had a potential for exposure similar to the previously studied tract (5120.12) during the period covered by the original study, 1980-81, and the follow-up period, 1982-85, and compare these rates to an additional unexposed area.

3. To determine if exposure to various levels of contaminated well water were associated with differences in rates of adverse pregnancy outcomes. Classification of environmental levels of water contamination in the study areas are described in the GOWDS (2).

Methods, results and conclusions for the third objective are presented in a separate section following the methods, results and discussion for the first two objectives.

METHODS

Definition of Adverse Pregnancy Outcomes

This study focused on the following three classes of adverse pregnancy outcomes:

(1) Spontaneous abortions: fetal losses occurring at less than 20 weeks gestation.

(2) Congenital anomalies: codes 740-759.9 of the International Classification of Disease, 9th Revision, Clinical Modification, diagnosed at birth or within the first six months of life. The term "congenital anomalies" refers to a combination of "congenital

malformations," due to poor formations, and "congenital deformations,"due to mechanical constraint forces.

(3) Low birth weight: Newborns weighing less than 2500 grams at birth.

For completeness, data also was collected on stillbirths. However, since these are rare events, the study did not have adequate statistical power to detect even large differences in the occurrence of stillbirths between exposed and unexposed areas.

Selection of Study Areas

The original exposed tract (5120.12) was chosen because it was presumed to have received water from the contaminated well and because of concerns of residents in that area. Census tract 5120.08 was chosen as the comparison census tract for 5120.12 because the two tracts had similar demographic characteristics, were near to each other geographically and the water supply for tract 5120.08 was shown to be free of contamination by TCA and DCE in 1982. Similar criteria were used to select a comparison area for tract 5120.11. Census tract 5120.11 was chosen because the limited exposure information available at the beginning of this study suggested that this tract had exposure to Well #13 water which was comparable to tract 5120.12.

There are essentially three sources of home tap water in Santa Clara County: ground water, surface water and mixed ground and surface water. GOWC used ground water. The only other water company in central SCC which primarily provides ground water and whose water showed no contamination with TCA or

other volatile organics in recent sampling was the City of Santa Clara Water Company. For this reason, we limited our search for a comparison area for tract 5120.11 to the city of Santa Clara. In this area, two adjacent tracts, 5053.02 and 5053.04, were demographically the most similar to 5120.11. Both were used to achieve a sample size comparable to 5120.11. They were treated as a single entity in the study and for convenience are referred to as 5053.0204.

For simplicity in what follows, the original census tracts, 5120.12 and 5120.08, will be called the "original study areas" and the census tracts added for this study, 5120.11 and 5053.0204, will be called the "new study areas." Figure 1.1 shows the location of these areas in Santa Clara County.

Table 2.1 presents demographic characteristics and fertility of women residing in the four areas obtained from the US Census (1980).

Enumeration of Pregnant Women in the Study Areas

In 1986 CDHS staff obtained addresses of all households in the four study areas from the Center for Urban Analysis in San Jose. We then enumerated members of each household living in the study areas by mail, phone, or home visit in order to locate women who had been pregnant in 1980 to 1985. The informant, preferably the female head of household, was asked to list all household members on a standard form and indicate any pregnancies occurring in the study period. Copies of the letters and enumeration form are presented in Appendix A.

Some men filled out the census form even though we requested that women provide the information. To assess whether male respondents reported all pregnancies, we reenumerated a 10% sample of the forms completed by men which indicated that a woman of reproductive age lived in the household but which did not report any pregnancies for the woman. We contacted the oldest female between the ages of 18 and 45 in each household and asked if there were any pregnancies during the study period among women in the household.

<u>Interview Methods to Ascertain Information on Pregnancies</u>

Information from the enumeration forms was used to identify women aged 15-49 who were pregnant anytime in 1980 through 1985. These women were then sent a letter explaining the study and requesting their participation in a telephone interview. The letter was followed by a telephone call from a trained CDHS interviewer. Women who could not be reached by phone were contacted in person. Consenting women were interviewed in detail about their pregnancies that occurred between 1980 and 1985. Pregnancy eligibility was determined by interviewers using the criteria below. Outcomes of eligible pregnancies and maternal and paternal factors which might be related to the pregnancy outcomes were assessed via questionnaire.

Eligibility criteria for each reported pregnancy were:

1. Live birth, stillbirth, or spontaneous abortion.

2. Estimated date of conception on or after January 1, 1980.

3. Pregnancy terminated on or before December 31, 1985.

4. Woman lived in the study area the entire time of her pregnancy.

Copies of the questionnaire and letter are included in Appendix A.

Validation of Spontaneous Abortions

Reports of spontaneous abortions were validated as soon as possible after the interview. Validation was achieved through the woman's attending physician or through additional interviews conducted by a CDHS physician or nurse. The validation forms are presented in Appendix A.

Spontaneous abortions were then categorized as either definite, probable, possible, not a spontaneous abortion or not validatable. Only definite spontaneous abortions were included in the analysis. A definite spontaneous abortion was one confirmed by a MD or medical record which indicated a dilation and curettage (D&C), or a positive pregnancy test with an appropriate clinical course. A probable spontaneous abortion was a pregnancy identified by a positive home pregnancy test, but having an atypical history or a pregnancy of at least six weeks after the last menstrual period (LMP) with positive symptoms of pregnancy and a typical history. Late, painful menses (less than six weeks post LMP) with symptoms of pregnancy or a late, painful menses without symptoms of pregnancy (at least six weeks post LMP) was categorized as a possible spontaneous abortion. A therapeutic abortion, ectopic pregnancy or a reported

spontaneous abortion with a totally atypical history was categorized as "not a spontaneous abortion". If a women reported a spontaneous abortion during the initial telephone interview but no MD report or medical records were available and the women herself was unavailable for an interview by CDHS medical staff, the spontaneous abortion was categorized as not validatable.

In the previous interview study (1), Kaiser Health Plan was sent the names of all women in the study areas who had not been enumerated as pregnant in 1980-81. Approximately 21%, or 732, of these women were Kaiser members. Their medical records for 1980 and 1981 were then reviewed. Of these 732 women, 95% had, in fact, no record of having been pregnant in 1980 or 1981. Of the remainder, most pregnancies resulted in therapeutic abortions. Only one spontaneous abortion was identified in the review. As a result of this effort we are reassured about the nearly complete ascertainment of spontaneous abortions which occur in pregnancies for which medical care has been sought. Therefore, this type of validation was not repeated in this current study.

Validation of Birth Defects

Reported birth defects were first reviewed by a CDHS physician. Suspected defects were then validated through physician report or medical or hospital record review. A physician from the California Birth Defects Monitoring Program (CBDMP) reviewed all suspected reportable defects and classified them according to criteria used by CBDMP as: 1) a CBDMP reportable malformation, 2) a CBDMP reportable deformation, 3) a CBDMP non-reportable defect, or 4) not a defect (3).

In the previous study (1) we reviewed the medical records from the hospital of birth for a random sample of 300 children whose mothers were interviewed and reported no congenital anomalies. Only one of these children had a birth defect noted on the medical record, indicating no serious under-reporting. We did not repeat this validation of negative responses in this study. Also in the previous study, birth certificates were used to identify suspected congenital anomalies in children born to parents living in any of the study areas at the time of birth, but whose parents moved after the child's birth and therefore were not enumerated at the time of census. In this way, four congenital anomalies among 287 live births were identified. Because there is little information on maternal risk factors for congenital anomalies on birth certificates, data on congenital anomalies obtained from birth certificates are of limited value. Thus, we did not repeat the review of birth certificates to identify congenital anomalies in children born to parents who were not identified in the enumeration.

Identification of Low Birth Weight Babies

The occurrence of low birth weight babies was ascertained differently than spontaneous abortions or congenital anomalies. Birth weight as reported on birth certificates in the vital statistics file for SCC were obtained for all live births to women who were residents in the study areas at the time of delivery and had an estimated date of conception between January 1, 1980 and December 31, 1984. Separate analyses were conducted for births to all women who were residents in the study area at the time of delivery whether or not they were interviewed and for births to those women identified in the interview study who resided in the study area for their entire pregnancy.

Analytic and Statistical Methods

Spontaneous Abortions:

Numerators for spontaneous abortion rates were those spontaneous abortions classified as "definite" after validation. Denominators were definite spontaneous abortions plus live births. Rates were computed for each study area and year and for the two time periods 1980-81 and 1982-85. Only pregnancies with estimated dates of conception prior to April 1985 were included in the analyses of spontaneous abortions because the final eligibility date of December 31, 1985 precluded full term births with later conception dates. For the original and new study areas, unadjusted odds ratios and 95% confidence intervals comparing the exposed to unexposed areas were computed for each year and grouped time period.

Spontaneous abortion rates and 95% confidence intervals were also computed for numerous potential covariates. Definite malformations were subtracted from the live births for these comparisons to eliminate the possibility of diluting any associations. Multiple logistic analyses were used to assess effects of study areas and time periods while controlling for potential covariates. A variable was included in the logistic analyses if its unadjusted relative risk for high to low risk category was statistically significant at the .05 level or was greater than or equal to 2.0 regardless of significance level. Women who reported IUD use (n = 17) at the time of pregnancy were excluded from the logistic analyses to restrict analysis to idiopathic spontaneous abortions. Women reporting use of water from a

private well (n = 5) were also excluded because their water source was not one of those under study.

Because of the lack of independence of multiple pregnancies occurring in the same woman and resulting bias in spontaneous abortion rates which are based on all pregnancies, analyses of spontaneous abortions were based on a single randomly chosen eligible pregnancy per woman. For purposes of comparison, rates and unadjusted comparisons between areas and time periods were also computed for all reported pregnancies.

Birth Defects:

Numerators for birth defect rates were birth defects classified as CBDMP reportable malformations after validation. Denominators were all reported live singleton births. Rates were computed for each study area and year and for the two time periods 1980-81 and 1982-85. For the original and new study areas, unadjusted odds ratios and 95% confidence intervals comparing the exposed to unexposed areas were computed for each year and grouped time period.

Birth Weight:

Low birth weight rates were calculated for 1980-85 in the four study areas; numerators were numbers of babies with birth weight less than 2500 grams; denominators were all live singleton births. Computations were made for all births with certificates and for those births to interviewed women. Births to women reporting diabetes or rubella during pregnancy were excluded.

Analysis of births to interviewed women were based on a single randomly chosen eligible pregnancy per woman. Unadjusted odds ratios and 95% confidence intervals comparing exposed to unexposed areas for the years 1980-81 and 1982-85 were computed separately for the original and new study areas.

Variable classification criteria:

Methods for classifying most variables were based on precoded interview questions. Methods for coding and classifying occupation and industry, chemicals and medications were more complicated and are presented here.

Occupations and Industries: All mothers' and fathers' job histories were coded according to the 1980 Bureau of Census Occupation and Industry three digit codes by a trained research assistant unaware of pregnancy outcome. Occupational exposures were analyzed for first trimester employment only. Codes were grouped into three industries of particular interest (electronics, health care and child care), three related occupational groups, (electronics workers, health care workers and child care workers), solvent exposed occupations, and sedentary versus non-sedentary occupations. The electronics industry and occupations were of interest because of potential exposure to organic solvents, while the health care industry and occupations were of interest because of potential exposure to biologic and pharmaceutic agents. Census codes for the electronics industry included electronic components, computers and communication equipment while occupational codes included operator, printer, metal plater and assembler. The codes for health care industry included hospitals, doctor's offices and

laboratories. Child care providers formed a separate industry category. Health care occupations included physicians, nurses and allied health care professionals. Again, child care providers formed a separate occupation category. Classification of solvent exposed occupations was much broader and included a list compiled by CDHS industrial hygienists and occupational physicians of 35 probably exposed and 37 possibly exposed occupations (see Appendix B). For the comparison of sedentary and non-sedentary occupations, secretaries, typists and general office clerks were classified as sedentary while teachers and waitresses were classified as non-sedentary.

Chemicals: Responses to an open-ended question (with specific prompting for solvent exposure) regarding exposure to chemicals or solvents at home or at work, or in some other activity during the first trimester, were categorized as solvent, gasoline, or pesticide exposure. Gasoline exposure referred to exposure to gasoline at self service stations. An insufficient number of women reported lead exposure or specific solvent exposures to allow analysis by these exposures.

Medications: Based on frequency of response, responses to an open-ended question regarding first trimester use of prescription medications were classified into the following 10 categories: tetracycline, other antibiotics, antihistamines, estrogens, corticosteroids, narcotics, fertility medications, thyroid medications, pain medications, and prenatal vitamins.

RESULTS

Enumeration:

A total of 10,063 households were enumerated between April and October, 1986. Distributions of response rates by method of enumeration for each study area are shown in Table 2.2. Refusal rates were very low in the four areas but were somewhat lower in the exposed areas (2.5% and 2.6%) than in the unexposed areas (3.7% and 4.2%). Across all areas the refusal rate was 3.3%, and the vacancy rate 3.4%. Another 1.2% of households did not appear vacant, but no response was obtained after seven door-to-door visits and 0.5% households could not be enumerated because of language problems. This gave an overall response rate of 91.6%.

Approximately 360 forms were completed by men who reported no pregnancies but indicated that a woman of reproductive age lived in the household. A total of 114 households were randomly selected from these to be reinterviewed. Women in 28 (25%) of these households could not be reached by phone for further questioning about their pregnancy history. Of 110 women listed in the remaining 86 households, only two were reported to have pregnancies upon telephone interview with women in the household. If this group of households were representative of the other households in which men reported no pregnancies in women of reproductive age, only about eight women with potentially eligible pregnancies would have been missed in our study.

Numbers of Women Interviewed and Pregnancies Reported:

According to the household enumeration a total of 2,713 women were reported to be pregnant sometime during the study period. Of these, 2,581 (95%) were interviewed; two percent refused and we were unable to locate or had language difficulties with three percent. Of interviewed women, 1,476 reported no eligible pregnancies and 1,105 women reported one or more eligible pregnancies (Table 2.3). Numbers of pregnancy outcomes reported per woman and the distribution of outcomes for eligible pregnancies are given in Table 2.4.

Spontaneous Abortions:

Results of validation of 260 reported spontaneous abortions are shown in Table 2.5; 211 (81.2%) were considered definite. Of these 211, 181 were conceived prior to April, 1985 and therefore are included in subsequent analyses.

The crude spontaneous abortion rate among all reported pregnancies conceived January 1, 1980 - April 1, 1985 was 13.2%. Multiple pregnancies per woman are not independent events and number of subsequent pregnancies depends on pregnancy outcome. Thus, the 13.2% is an overestimate of the spontaneous abortion rate. The rate based on a single randomly chosen pregnancy per woman was 9.9% (Table 2.6).

The numbers of definite spontaneous abortions and live births by study areas, years, and grouped time periods are given in Tables 2.7 and 2.8. The

spontaneous abortion rates are shown in Table 2.9. The rates range from a low of 0% in 1980 in the original control area (5120.08) to 28.6% in 1985 in the new control area (5053.0204). There are no apparent trends with year, grouped time period, or exposure status. Appendix C fits the spontaneous abortion rates by census tract and area to the normal distribution expected if all the rates came from a single binomial distribution. Even though the rates appear to be quite variable they are compatible with those expected by chance.

Odds ratios and 95% confidence intervals for spontaneous abortions in exposed versus unexposed areas for each year and grouped time periods for the original and new study areas also show no trends. Thus, these data are not consistent with the hypothesis that the leak was associated with the increased rate of spontaneous abortions observed in 5120.12 in 1980-81 (Table 2.10).

As in the first interview study (1), the odds ratio for the original exposed versus the original unexposed area for 1980 and 1981 was significantly greater than one (OR = 3.52; 95% CI: 1.21, 10.31). However, the odds ratio for the new study areas for 1980 and 1981 was less than one (OR = 0.32; 95% CI: 0.09, 1.14). Combining the original and new study area for 1980 and 1981 yields an odds ratio for exposed versus unexposed areas of 1.4 (95% CI: 0.9, 2.1). For 1982-85, the post-exposure time period, the odds ratios for the original study areas is 1.00 and for the new study areas is 1.31; combining the original and new study areas yields an odds ratio of 1.1, (95% CI: 0.8, 1.3).

Table 2.11 compares the spontaneous abortion results from this study with those found in the original study (1) conducted in 1983. As shown, the estimated odds ratios for exposed to unexposed area in 1980-81 were very similar from the two studies: this study gave slightly higher relative risks estimates than the original study.

Tabulations of spontaneous abortions rates and odds ratios by census tracts and years using all eligible pregnancies are contained in Appendix D. Tabulation of stillbirths by year and area are also in Appendix D.

Spontaneous abortion rates and 95% CIs for numerous potential risk factors and other covariates are presented in Table 2.12. Variables for which there was at least a 2-fold relative risk between highest and lowest risk category (and for which there were more than 10 pregnancies for highest and lowest risk category) or for which the relative risk was significantly greater than 1 included: woman's age at pregnancy, number of previous spontaneous fetal losses, month prenatal care began, IUD use at time of pregnancy, first trimester bleeding, nausea, nausea medication use, prenatal vitamins, antibiotics, alcohol use, probable solvent exposure at work, father's occupation of electronics worker or health care worker, used water from a private well, water filter use around the time pregnancy began, mother's and father's ethnicity, first trimester cold tap water consumption, and bottled water use anytime during pregnancy.

In addition, average gestational weeks differed among time periods and study areas (Table 2.13).

To decide if any of these factors might alter the odds ratios for area and time period, several mutiple logistic models were considered. Using the established criteria, a preliminary model was fit that included study area (four census tracts), time periods (1980-81 and 1982-85), an interaction between census tracts and time periods, any vs. no home cold tap water, maternal age ($\leq$ 20, 21-34, 35+), number of previous miscarriages or stillbirths (0, 1, 2 or more), ethnicity (White or Hispanic versus others), alcohol consumption (< 4 drinks/week, 4+ drinks per week), probable versus not probable solvent exposure on the job, father's occupation as electronics worker, father's occupation as health care worker, and water filter use around time pregnancy began. Despite its lack of association to spontaneous abortion, smoking (none, $\geq$ 1/2 pack per day, or about a pack a day or more) was included in the model because of the reported association between smoking and SAB in other studies (4). Use of prenatal vitamins or antibiotics was not included in the model (in spite of the observed association with spontaneous abortion) because their use varied with pregnancy length and month prenatal care began. Furthermore, specific drugs were not solicited and may be over or underreported among women with different outcomes. Bleeding was not included in the model because it may be the first symptom of spontaneous abortion. Bottled water was not included in the model because we did not ask first trimester use; women with live births would have five to seven months more time to have drunk bottled water during their pregnancy than women with SABs. Results for the preliminary model using father's occupational variables are not presented because these variables were not found to significantly contribute to the model or to alter the other parameter estimates when included or excluded from the model and missing data for these variables reduced the number of

pregnancies that could be analyzed (number with missing information = 38). Results for seven other models are presented in Appendix E. Model 1 uses all the variables listed above except father's occupational variables; model 2 used only White and Hispanic women; model 3 used only women reporting first trimester nausea; model 4 used only women reporting no nausea during the first trimester; model 5 used only pathology confirmed SABs; model 6 used only early SABs (those with estimated gestational week of nine weeks or less); and model 7 excluded pregnancies conceived in 1980 because of the uncertain contamination status of the water in 1980.

In order to provide confidence limits for the odds ratios associated with study areas and time periods and with water filter use among tap water and non-tap water drinkers a final model (model 8) was fit which entered the eight census tract and time period combinations as a single variable and four water filter use and cold tap water use combinations (Table 2.14). The parameter estimates of the other covariates in this model are very similar to those found in model 1. To summarize the results for model 8, women under 20 or over 34 were more likely to have an SAB (p=.001), as were women with prior fetal loss (p=.10). Whites and Hispanics had higher rates of SAB than other ethnicities (p = .01) and women classified as having jobs that probably involved solvent exposure had elevated odds ratio compared to other women (p=.008). Women reporting cold home tap water use without filters were 5.5 (95% CI 2.1, 14.0) times as likely to have had SABs as those using no tap water while women consuming tap water but using filters were only slightly more likely to have had SABs than non-tap water drinkers OR = 1.6, (95% CI: 0.3, 8.6). A separate CDHS document (5) further explores this association. Neither alcohol consumption nor smoking were significantly

related to occurrence of SAB (p=.60 and .94 respectively). All of the ORs for study areas and time periods were less than the original exposed area during 1980-81, but only the new exposed area for 1980-81 and the original control area for 1980-81 had odds ratios significantly less than the original exposed areas. The odds ratios in Table 2.14 are also rearranged to enable easy comparison to the unadjusted odds in Table 2.10, and are quite similar to the unadjusted ORs.

None of the models presented in Appendix E altered the basic impression that the odds ratio of spontaneous abortion was only elevated in the original exposed study area in 1980-81 and that the odds ratio was equally elevated relative to both the original control area and the new exposed area during that time. Omitting pregnancies conceived in 1980 (model 7) had very little effect on the estimated odds ratios.

Some other results are of interest in comparing models 1 through 6. The model restricted to Whites and Hispanics (model 2) gave very similar results to the model that included ethnicity as a parameter (model 1). Women reporting first trimester nausea (model 3) appeared to have different patterns of odd ratios for some factors than women reporting no nausea (model 4). Of interest, women reporting nausea compared to non-nauseous women had higher odds ratios for tap water consumption, alcohol use, and probable solvent exposure.

Among pathology confirmed spontaneous abortions (model 5) compared to all definite spontaneous abortions (model 1), odds ratios were somewhat lower (closer to unity) for tap water use and two or more prior fetal losses. The

odds ratio for non-White or non-Hispanic ethnicity were even lower and the odds ratio for probable solvent exposure even higher among the pathology confirmed cases. No pathology confirmed SABs occurred among women reporting filter use.

Odds ratios for prior spontaneous fetal loss were higher among early spontaneous abortions (model 6) than all definite spontaneous abortions (model 1). None of the women classified as probably solvent exposed had early spontaneous abortions yielding a very low estimated odds ratio for this factor.

Birth Defects:

Table 2.15 presents results of the validation of all reported birth defects. One hundred sixteen women reported having a child born with a birth defect during the study period. Of these, 36 (32%) validated birth defects met the CBDMP classification of a reportable malformation and one validated case met the CBDMP classification of a reportable deformation. Diagnoses of cases of congenital anomaly by study area, month and year of birth are presented in Table 2.16. The anomalies are grouped into malformations and deformations.

Only one of the 37 cases of a reportable defect was an isolated deformation. Therefore, the remainder of the analysis included only the 36 malformations.

Numbers of reportable malformations, numbers of singleton births, and malformation rates by census tracts and years are presented in Tables

2.17-2.19. Table 2.20 presents odds ratios and 95% confidence intervals for all reportable malformations in exposed versus unexposed areas by time period. A four-fold excess of birth defects is seen in the original exposed census tract for the period 1980-81. However, the new exposed census tract demonstrates a deficit for this time period. During the 1982-85 study period a slight, non-significant excess in birth defects among exposed compared with unexposed census tracts was found.

Malformation rates and odds ratios were computed for the following potential covariates: parental ethnicity , education and occupation, mother's work schedule, chemical exposure, home pest control application, diabetes, hypertension, prescription medications, IUD use, amniocentesis, chorionic villus sampling, x-ray exposure, fever, nausea, alcohol consumption and cigarette smoking. For those exposures which might not have been constant throughout the pregnancy, first trimester exposure was examined separately. Covariates associated with a 2-fold or greater increase in risk of malformations among those exposed compared to those unexposed to the factor are as follows: narcotic use, chest x-ray first trimester, a work schedule involving rotating between two work shifts and father's occupation in childcare. For each of these covariates only one malformation occurred among women exposed to the factor. First trimester alcohol consumption was associated with a 2-fold deficit in the malformation rate among exposed.

Although the number of cases of any specific defect was very small in this study, rates for specific defects among study participants were calculated and are presented in Table 2.21. This table contains a list of all categories of congenital anomalies for which published CBDMP rates are

available. In determining rates, children with multiple defects are included in more than one category. Rates from the Centers for Disease Control program in the Atlanta Metropolitan Area are given as an additional comparison rate. No condition occurred more than four times in the study population with the majority of conditions appearing only once. Because of the small number of overall cases (37) the rates for individual conditions are very unstable and therefore, of limited value. This table also demonstrates the numerous conditions which are equally prevalent in the general population but did not occur among the study area population.

Of the conditions which occurred among children born in the four study areas but which are not in the CBDMP published list, only four conditions occurred more than once: cardiac malformations, (ICD9-CM-745.4,.5) (n=2), undescended testicle (ICD9-CM-752.5) (n=2), duplicated ureter,(ICD9-CM-753.4) (n=2), pectus excavatum (ICD9-CM-754.81) (n=2), for a rate of 1.71/1000 live births for each condition.

Table 2.22 lists covariates of interest for the four categories of congenital malformations occurring in more than two children: pyloric stenosis, anomalies of the genitourinary system, hypospadius and syndactyly. No pattern of risk factors are common to a specific malformation.

Birth Weight:

Numbers of low birth weight babies, numbers of singleton births, and low birth weight rates from all certified births by census tract and years are shown in Tables 2.23 to 2.25. Rates in the grouped time periods ranged from a low of 1.5 in the new unexposed (5053.0204) area in 1980-81 to a high of 4.8 in the new exposed area (5120.11) in 1982-85; there were no apparent trends in rates among study areas or time periods. In the original study area, low birth weight occurred somewhat less frequently in the exposed compared to the unexposed areas in both time periods OR (1980-81)= 0.7; OR (1982-85) = 0.6 (Table 2.26). The occurrence of low birth weight was somewhat higher in the exposed versus unexposed new study areas OR (1980-81) = 1.7; OR (1982-85) = 1.2. Combining the original and new study areas, the odds ratios for low birth weight in exposed versus unexposed areas were 1.07 for 1980-81 and .98 for 1982-85.

In the analysis of low birth weight among all certificated births the following risk factors of low birth weight were evaluated as potential confounders; mother's age, race, pregnancy complications (pre-eclampsia, eclampsia), presence of and time of prenatal care, previous spontaneous fetal loss, prematurity (< 36 weeks gestational age), parity (nulliparity or more than four prior births versus 1-3 prior births), and infant's sex. Adjustment for these factors individually using the Mantel-Haenszel method, or simultaneously using logistic regression did not alter the odds ratios associated with time periods and study areas.

Results for births to interviewed women were similar to results for all certificated births, (Tables 2.27 to 2.30). The estimated odds ratio for 1980-81 births was lower in the original study areas (0.3 for interviewed women compared to 0.7 for all certificated births) but was higher in the new study areas (4.4 for interviewed women versus 1.7 for all certificated births). All of the 95% CIs included unity.

In addition to factors examined in relation to low birth weight in all certificated births, first or second trimester bleeding or nausea, maternal smoking and drinking habits, mother's and father's education and employment status, mother engaged in shiftwork or worked more than 40 hours per week, and mother's ponderal index were also examined in interviewed women. Only variables found to be significantly associated with low birth weight were included as potential confounders in multiple logistic analyses. These variables were: any vs. no cigarette smoking, premature delivery (<36 weeks), low weight gain (< 20 lbs) (models were examined which included and excluded these variables), previous spontaneous fetal loss, first trimester alcohol consumption (none, 1-3 drinks/week, 4 or more drinks/week), nausea during second or third trimester, and job in the electronics industry (yes: % low birth weight = 14.8%, n = 27; no: % low birth weight = 3.0%; n = 871; p = .001). The observed lack of relationship of low birth weight to study areas and time periods persisted after adjustment for these factors.

DISCUSSION

Spontaneous Abortions

Overall rates of definite spontaneous abortion of 13.2% (among all eligible pregnancies per woman) and 9.9% (among a single eligible pregnancy per woman) are compatible with published rates of spontaneous abortion among recognized pregnancies. The most often cited rates range from 10-20% (4, 6) but rates as low as 7% have been reported (7). This combined with enumeration and interview response rates exceeding 90% and with the evidence from the original study (1) that there was very little underreporting of pregnancies among enumerated Kaiser Health Plan members suggests that we had satisfactory ascertainment of pregnancies. This conclusion may not apply to Asians who had a significantly lower spontaneous abortion rate (4.2%). Average gestational age of five spontaneous abortions to Asian women (mean age = 14.20 weeks) were somewhat greater (p=.08) than those to 98 White or Hispanic women (mean age = 11.0 weeks) suggesting that Asian women with early SABs may have been less likely to have been enumerated as pregnant.

Associations observed between spontaneous abortion and woman's age at pregnancy, prior spontaneous fetal loss, and nausea are consistent with other studies (4, 8). Although not statistically significant, there was a two-fold relative risk for spontaneous abortion associated with consuming four or more alcoholic drinks per week in univariate analysis; the odds ratio was reduced to 1.4 after adjustment for other factors but was 2.3 in the model restricted to women reporting nausea. Associations of alcohol

consumption and SAB in other studies have not been totally consistent but suggest a deleterious effect of alcohol consumption (4, 9).

The unadjusted odds for spontaneous abortion and cigarette smoking suggested a modest association in this population (OR=1.9). However, the adjusted odds for smoking one or more packs a day were very close to unity in all models except that restricted to early spontaneous abortions (OR=2.0). Other studies have reported significant associations of smoking with spontaneous abortions, but the relative risks were well below two among light smokers in one study (9) and did not hold after adjustment for maternal age, social class, and oral contraceptive use in another study (reviewed in 4).

The elevated, unadjusted odds ratio for spontaneous abortion among those classified as probably occupationally exposed to solvents persisted after adjustment in all models except the model restricted to early spontaneous abortions. As with alcohol exposure, the estimated odds ratio for occupational solvent exposure was highest in the model restricted to women reporting first trimester nausea. Although recall bias is a possible explanation for these findings, the initial categorization of solvent exposed occupation was made on occupational code alone. Only after a job was categorized on that basis were the job activities and reports of solvent exposure used in making the classification of probable solvent exposure. Solvent exposure has been implicated in spontaneous abortion risk but not consistently so (10). A nearly completed CDHS study will more thoroughly address the possible association between parental solvent exposure and spontaneous abortion.

A separate report discusses at length the finding that consumption of unfiltered tap water is significantly associated with spontaneous abortion independent of study area or time period (5).

To summarize, our findings are consistent with other studies with respect to observed rates and risk factors for spontaneous abortion. Furthermore, our results for the original study areas and the original time period (1980-81) are very consistent with those reported for the original study. This suggests that potential differential migration out of the exposed area either did not occur or was of insufficient magnitude to seriously alter the observed odds ratio for exposure in the original areas and time period. It seems unlikely, therefore, that we would fail to detect an elevated odds ratio for exposure among 1980-81 pregnancies in the new study areas if it had occurred. In fact, we observed a non-significant odds ratio of less than one for exposure in the new study areas in 1980-81 and an overall odds ratio of very close to one after combining the original and new study areas. Adjusting for covariates did not alter these findings. Given that the new exposed area (5120.11) was more likely to receive water from Well #13 [see Great Oaks Water Distribution Study (2)], it seems very unlikely that the observed excess of spontaneous abortions in the original study area (5120.12) would be due to exposure to water from Well #13. A subsequent section presents more detailed exposure analysis of 1981 pregnancies in areas 5120.11 and 5120.12.

Birth Defects and Birth Weight

As with spontaneous abortions, our overall rates of birth defects and low birth weight are similar to published rates from other studies (See Table 2.21 and Reference 11). The findings for original study areas and time periods are quite similar to those reported in the original study (1); there was an excess of malformations and a deficit of low birth weight babies in the original exposed area in 1980-81. However, there was a deficit of malformations and an excess of low birth weights in the new exposed area in 1980-81 so odds ratios of exposure in 1980-81 for either malformations or low birth weight were close to unity when the original and new areas were combined.

ANALYSES OF 1981 PREGNANCY OUTCOMES IN RELATION TO HYDROGEOLOGIC EXPOSURE ESTIMATES

Methods

Exposure estimates:

The Great Oaks Water Distribution Study (GOWDS) provided estimates of the probability of receiving water from Well #13 of the GOWC for each month in 1981. The estimates for each node (junctions of water distribution pipes) apply to a group of addresses around that node. The study further provided estimates of the proportion of each month that Well #13 was operational and of the concentration of TCA in water from Well #13 each month. The author of GOWDS calculated these estimates with no knowledge of the distribution of pregnancy outcomes in the census tracts. The limitations of these estimates are presented in the report (2).

We assigned a node number to the addresses of each reported eligible pregnancy conceived in 1981 in census tracts 5120.12 and 5120.11. The estimated exposure to water from Well #13 for the 1st, 2nd and 3rd months of each pregnancy were then obtained for the appropriate node and months from Table 14 in the GOWDS (2) and multiplied by the percent of each month that the Well #13 was pumping. Each probability was then multiplied by the estimated concentration of TCA in Well #13 water for the appropriate month to give an estimated TCA exposure for the month. Cumulative exposure for the first two or the first three months of pregnancy were obtained by adding the estimates for the first two months and for the first three months of pregnancy. It was assumed that the probability of exposure was zero after December 31, 1981. The maximum of the two probabilities of exposure to Well

#13 water for the first two months of pregnancy and of the three probabilities of exposure for the first three months of pregnancy were also analyzed, as were the cumulative probabilities of no exposure to Well #13 water during the first, the first two and the first three months of pregnancy.

Statistical Methods

Comparisons of estimated TCA exposures and probabilities of exposure to Well #13 were made with analysis of variance (to compare means) and Wilcoxon rank sum tests (to compare medians).

Results

Spontaneous Abortions

Estimated TCA exposure for the first month of pregnancy and estimated cumulative TCA exposure for the first two months and first three months of pregnancy were very similar among pregnancies ending in live births versus those ending in SAB (Table 2.31A). This was true using either all reported pregnancies per woman or using a single random eligible pregnancy per woman. Similar results were obtained when exposure was assumed to be zero for women who reported either no home tap water consumption during the first trimester or use of a water filter beginning around the time of conception. Using all reported SABs or only those considered "definite" SABs upon validation did not alter the results. Futhermore, percent distributions of spontaneous abortions and live births (excluding those born with defects) by quartiles of estimated TCA exposure during the first month of pregnancy did not indicate increasing risk of spontaneous abortion with increasing estimated TCA exposure in either census tract 5120.11 or 5120.12 (Table 2.31B).

Similarly, no differences were detected in the probabilities of exposure to water from Well #13 between pregnancies ending in live births and those ending in spontaneous abortion (Tables 2.32 and 2.33).

Birth Defects

The six live births classified as CBDMP reportable malformations occuring in 1981 had significantly less cumulative exposure to TCA, lower maximum probability of exposure to water from Well #13 and higher cumulative probability of no exposure to water from Well #13 during their first trimester than live births without reportable malformations (Table 2.34).

Conclusion

These results support the finding that exposure to contaminated drinking water from Well #13 was not related to risk of spontaneous abortion or birth defects in pregnancies conceived in 1981.

References

1. Epidemiological Studies Section, California Department of Health Services: Pregnancy Outcomes in Santa Clara County 1980-1982: Reports of Two Epidemiological Studies. California State Publications Section. Report 7540-958-1301-5, 1985.

2. Murphy P: The Great Oaks Water Distribution Study, 1988.

3. California Birth Defects Monitoring Program: Procedure Manual Vols I and II California Department of Health Services, Berkeley 1984.

4. Kline J, and Stein Z: Spontaneous abortion in Perinatal Epidemiology, M Bracken, (ed.) Oxford Univ. Press, London, 1984; 23-51.

5. California Department of Health Services: Water Exposure and Pregnancy Outcome, 1988.

6. Warburton D: Effects of common environmental exposures on spontaneous abortion of defined karyotype. In: Prevention of Physical and Mental Congenital Defects, Part C: Basic and Medical Science, Education, and Future Strategies 1985; 31-36.

7. Hemminki K, Niemi ML, Saloniemi I, Vainio H, Hemminki, E: Spontaneous abortions by occupation and social class in Finland. Int. J. Epidemiology 1980; 9:149-53.

8. Petitti, DB: Nausea and pregnancy outcome. Birth 1986; 13(4): 223-226.

9. Kline J, Levin B, Stein Z, Susser M, Wharburton D: Epidemiologic detection of low dose effects on the developing fetus. Environmental Health Perspectives 1981; 42:119-126.

10. Lindbohm ML, Taskinen H, Hemminki K: Reproductive health of working women: Spontaneous abortions and congenital malformations. Public Health Rev. 1985; 13:55-87.

11. Kleinman JC, Kessel SS: Racial differences in low birth weight. N Engl. J Med 1987; 317:749-53.

Table 2.1

1980 U.S. Census Characteristics Used to Select Two Control Census Tracts for Two Census Tracts Served By GOWC

	GOWC Tracts		Control Tracts	
	5120.12	5120.11	5120.08	5053.0204
Median Housing Cost	$104,600	$101,800	$113,800	$ 94,800[a]
Median Persons Per Unit	3.2	3.6	3.2	2.9[a]
Median Age Females	26.6	25.1	26.5	30.4[a]
Race				
White	84.5%	81.0%	84.0%	80.1%
Black	3.6%	4.0%	2.9%	1.8%
Asian Pacific/Islander	6.8%	4.9%	6.9%	10.0%
Other	5.2%	10.1%	6.1%	8.1%
Spanish Origin[b]	11.2%	16.3%	12.5%	16.7%
Fertility[c]	82.0%	62.2%	60.7%	59.1%

[a]Numbers are the average of tracts 5053.02 and 5053.04.

[b]Persons of Spanish origin may be of any race.

[c]Defined as the number of live births divided by the estimated female population, age 15-44, multiplied by 1,000.

Table 2.2

Percent Distribution of Responses to Household Enumeration of Four Census Tracts in Santa Clara County

	Exposed		Unexposed		
	5120.12(0)	5120.11(N)	5120.08(0)	5053.0204(N)	[a]TOTAL
Response	%	%	%	%	%
Enumerated:					
1st mailing	37.1	35.3	31.2	31.9	32.1
2nd mailing	17.2	16.0	16.4	18.5	17.6
Door to door canvassing	39.0	41.4	42.3	41.3	41.6
Combinations of mailings and door to door	0.5	0.3	0.4	0.1	0.3
All Methods	93.8	93.0	90.3	91.8	91.6
Not Enumerated:					
Refusal	2.6	2.5	3.7	4.2	3.3
Vacancies	2.5	3.3	3.6	2.4	3.4
Unenumerable	1.0	0.9	1.7	0.5	1.2
Language Problem	0.1	0.3	0.5	1.1	0.5
All Reasons	6.2	7.0	9.5	8.2	8.4
TOTAL	2079	2637	3402	2373	10977

[a]Total is greater than the sum of the four areas because 486 additional eligible households were discovered after the first mailing. These households were enumerated with the second mailing and door to door canvassing. The refusal rate was 3.1 % and the vacancy rate was 9.5% in these households.

0=Original study area
N=New study area

Table 2.3

Response to Interviews Among Women For Whom Pregnancy was Reported in Enumeration

	N	%
Respondents:		
Women with 1 or more eligible pregnancies	1105	41
Women with no eligible pregnancies	1476	54
Non-respondents:		
Refused	45	2
Unable to locate and language problems	87	3
TOTAL	2713	100

Table 2.4

Number of Eligible Pregnancy Outcomes
Reported by Interviewed Women

N(eligible pregnancies)	N(women)	% Distribution
1	802	72.6
2	245	22.2
3	48	4.3
4	8	0.7
6	2	0.2
TOTAL	1105	100.0

Distribution of Outcomes Among Reported Eligible Pregnancies

Singleton Live Births	1199
Twin Births (5 twin pairs)	10
Spontaneous Abortion	260
Stillbirth	11

Table 2.5

Validation of Reported Spontaneous Abortions

Validation Categories:	N(SAB)	% Distribution
Included in analyses:		
Definite[a]	211	81.2
Not Included in analyses:		
Probable[b]	12	4.6
Possible[c]	13	5.0
Not a Spontaneous Abortion[d]	11	4.2
Not Validatable[e]	13	5.0
TOTAL	260	100.0

[a] Confirmed by MD or medical record, D & C or positive pregnancy test with appropriate subsequent clinical course.

[b] Positive home pregnancy test with an atypical history or a pregnancy of $\geq$ 6 weeks post LMP, with positive symptoms of pregnancy and a typical history.

[c] Late painful menses with symptoms of pregnancy if < 6 weeks post LMP, or without symptoms if $\geq$ 6 weeks post LMP.

[d] Therapeutic abortion, ectopic pregnancy or totally atypical history.

[e] Neither woman nor MD nor medical record available for validation and did not fit into above categories.

Table 2.6

Validated Definite Spontaneous Abortions Among All Pregnancies and Among a Single Randomly Chosen Eligible Pregnancy[a]

	N(SAB)	N(SAB + live birth)	Crude SAB rate%
Total File	181	1376	13.2
Random Eligible Pregnancy	103	1038	9.9

[a] Conceived prior to April 1, 1985

Table 2.7

Number of Definite Spontaneous Abortions[a] by Year and Census Tract

CENSUS TRACT

	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(O)	5120.11(N)	(BOTH)	5120.08(O)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	4	1	(5)	0	1	(1)	6
1981	9	3	(12)	5	5	(10)	22
(1980-81)	(13)	(4)	(17)	(5)	(6)	(11)	(28)
Unexposed:							
1982	2	3	(5)	7	2	(9)	14
1983	5	7	(12)	2	2	(4)	16
1984	12	8	(20)	11	2	(13)	33
1985	3	2	(5)	3	4	(7)	12
(1982-85)	(22)	(20)	(42)	(23)	(10)	(33)	(75)
TOTAL	35	24	(59)	28	16	(44)	103

[a] Number of spontaneous abortions among a single random eligible pregnanacy per woman.
O = Original study area
N = New study area

1583.1-11

Table 2.8

Number of Live Births[a] by Year and Census Tract

CENSUS TRACT

	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(O)	5120.11(N)	(BOTH)	5120.08(O)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	44	34	(78)	52	16	(68)	146
1981	32	48	(80)	51	22	(73)	153
1980-81	(76)	(82)	(158)	(103)	(38)	(141)	(299)
Unexposed:							
1982	43	54	(97)	32	31	(63)	160
1983	44	48	(92)	57	38	(95)	187
1984	52	77	(129)	55	47	(102)	231
1985	16	14	(30)	18	10	(28)	58
1982-85	(155)	(193)	(348)	(162)	(126)	(288)	(636)
TOTAL	231	275	(506)	265	164	(429)	935

[a] Number of live births among a single random eligible pregnancy per woman.
O = Original study area
N = New study areaa

Table 2.9

Spontaneous Abortion Rates[a] by Year and Census Tract

	CENSUS TRACT						
	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(0)	5120.11(N)	(BOTH)	5120.08(0)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	8.3	2.9	(6.0)	0.0	5.9	(1.5)	3.9
1981	22.0	5.9	(13.0)	8.9	18.5	(12.1)	12.6
(1980-81)	(14.6)	(4.7)	(9.7)	(4.6)	(13.6)	(7.2)	(8.6)
Unexposed:							
1982	4.4	5.3	(4.9)	18.0	6.1	(12.5)	8.1
1983	10.2	12.7	(11.5)	3.4	5.0	(4.0)	7.9
1984	18.8	9.4	(13.4)	16.7	4.1	(11.3)	12.5
1985	15.8	12.5	(14.3)	14.3	28.6	(20.0)	17.1
(1982-85)	(12.4)	(9.4)	(10.8)	(12.4)	(7.4)	(10.3)	(10.6)
TOTAL	13.2	8.0	(10.4)	9.6	8.9	(9.3)	9.9

[a] Among a single random eligible pregnancy per woman.
0 = Original study area
N = New study area

1583-3.11

Table 2.10

Odds Ratios and 95% Confidence Intervals for
Spontaneous Abortions in Exposed vs. Unexposed Areas by Year

	ORIGINAL STUDY AREAS (5120.12/5120.08)		NEW STUDY AREAS (5120.11/5053.0204)	
	OR	95% CI	OR	95% CI
Time period				
1980	10.62[a]	(0.56, 202.66)	0.48[a]	(0.05, 4.96)
1981	2.78	(0.86, 9.03)	0.30[a]	(0.07, 1.23)
(1980-81)	(3.52)	(1.21, 10.31)	(0.32[a])	(0.09, 1.14)
1982	0.25[a]	(0.06, 1.12)	0.81[a]	(0.15, 4.35)
1983	2.84[a]	(0.61, 13.33)	2.38[a]	(0.54, 10.59)
1984	1.15	(0.47, 2.84)	2.08[a]	(0.49, 8.93)
1985	1.12[a]	(0.22, 5.69)	0.40	(0.07, 2.29)
(1982-85)	(1.00)	(0.54, 1.87)	(1.31)	(0.59, 2.88)

[a]Small sample adjustment

Table 2.11

Comparisons of Ascertainment of Live Births and Spontaneous Abortions Conceived During 1980 or 1981 and Identified During a 1983 Interview Study and a 1986 Interview Study

	Census Tract 5120.12		Census Tract 5120.08	
	1983 Study	1986 Study	1983 Study	1986 Study
1980-1981 Live births	145	97	182	127
Definite SAB	35 (19.4%)	22 (18.5%)	21 (10.3%)	10 (7.3%)
All Reported SABs	40 (21.6%)	26 (21.1%)	22 (10.8%)	13 (9.3%)

	1983 Study	1986 Study
OR for definite SABs 5120.12 vs. 5120.08	2.1	2.9
OR for all reported SABs 5120.12 vs. 5120.08	2.3	2.6

Table 2.12

Spontaneous Abortion Rates by Selected Variables

Variable	SAB Rate (%)	N (Pregnancies)[a]	95% Confidence Interval
Woman's age at pregnancy			
≤ 20	17.4	69	(8.5, 26.4)
21-34	8.3	836	(6.4, 10.2)
35+	21.0	105	(13.2, 28.8)
Number of prior pregnancies			
0	10.1	298	(6.7, 13.5)
1	8.7	355	(5.8, 11.6)
2	8.5	200	(4.6, 12.4)
3 or more	16.0	156	(10.3, 21.8)
Number of previous spontaneous abortions or stillbirths			
0	9.3	829	(7.3, 11.3)
1	12.3	138	(6.8, 17.8)
2 or more	21.0	43	(8.8, 33.2)

[a] # spontaneous abortions + # live births - # birth defects among a single random eligible pregnancy per woman (overall SAB rate = 10.2%).

NC confidence intervals not calculated if rates based on fewer than five pregnancies.

Table 2.12 (Continued)

Variable	SAB Rate (%)	N (Pregnancies)[a]	95% Confidence Interval
Month prenatal care began			
1	14.4	313	(10.5, 18.3)
2	7.5	464	(5.1, 9.9)
3	4.1	172	(1.1, 7.1)
4+	0.0	41	NA
None	100.0	15	NA
Number of prior live births			
0	10.1	368	(7.0, 13.2)
1	9.7	402	(6.8, 12.6)
2	10.0	160	(5.4, 14.7)
3 +	13.8	80	(6.2, 21.4)
IUD use at time of pregnancy			
Yes	29.4	17	(10.5, 54.4)
No	9.9	986	(8.0, 11.8)
First trimester:			
Diabetes			
Yes	0.0	8	(0.0, 28.2)
No	10.3	998	(8.4, 12.2)

Variable	SAB Rate (%)	N (Pregnancies)[a]	95% Confidence Interval
Hypertension			
Yes	7.1	28	(0.9, 23.3)
No	10.3	978	(8.4, 12.2)
Fever			
Yes	9.1	33	(0.0, 18.9)
No	10.4	942	(8.5, 12.4)
Bleeding			
Yes	31.8	85	(21.9, 41.7)
No	8.6	924	(6.8, 10.4)
Nausea			
Yes	7.3	607	(5.2, 9.4)
No	14.4	396	(10.9, 17.9)
Nausea medication use among women who reported first trimester nausea			
Yes	1.3	75	(0.0, 3.9)
No	8.1	530	(5.8, 10.4)
Smoking first trimester			
None	9.4	862	(7.5, 11.4)
< 1/2 pk/day	12.9	93	(6.1, 19.7)
1+ pk/day	16.0	50	(5.8, 26.2)

Variable	SAB Rate (%)	N (Pregnancies)[a]	95% Confidence Interval
First trimester alcohol use			
None	9.9	669	(7.6, 12.2)
<4 drinks/wk	9.9	305	(6.6, 13.3)
4+ drinks/wk	19.4	31	(5.5, 33.3)
First trimester prescription medication use			
None	11.8	720	(9.4, 14.2)
Prenatal vitamins	3.1	32	(0.0, 9.1)
Antibiotics	3.7	27	(0.1, 18.9)
Antihistamines	9.1	11	(0.2, 40.5)
Estrogens	0.0	7	(0.0, 32.2)
Corticosteroids	50.0	2	NC
Anti-nausea	0.0	35	(0.0, 8.1)
Thyroid medication	7.1	14	(0.2, 31.8)
Non-narcotic pain medication	11.1	9	(0.3, 39.8)
Narcotics	11.1	9	(0.3, 39.8)
Diabetes medication	0.0	4	NC
Hypertension medication	0.0	3	NC

Variable	SAB Rate (%)	N (Pregnancies)[a]	95% Confidence Interval
Any employment during first trimester			
Yes	10.3	638	(7.9, 12.7)
No	10.2	363	(7.1, 13.3)
First trimester job involved:			
Probable solvent exposure	25.0	20	(6.8, 40.7)
Possible solvent exposure	6.3	16	(0.2, 30.0)
Non-sedentary work	11.9	42	(2.1, 21.7)
Sedentary work	13.5	96	(6.7, 20.3)
Industry			
Electronics	13.1	175	(8.1, 18.1)
Hospital	11.1	63	(3.3, 18.9)
Doctor's Office/Clinic	15.0	20	(3.2, 37.9)
Child Care	11.1	45	(1.9, 20.3)
Occupation			
Electronics	11.1	27	(2.4, 28.9)
Hospital	14.5	62	(5.7, 23.3)
Child Care	15.6	32	(3.0, 28.2)

Table 2.12 (Continued)

Variable	SAB Rate (%)	N (Pregnancies)[a]	95% Confidence Interval
Any first trimester shift work			
Yes	14.8	115	(8.3, 21.3)
No shiftwork	9.4	523	(6.9, 11.9)
Type of first trimester shift work			
Evenings	14.8	61	(5.9, 23.7)
Nights	10.0	10	(0.3, 44.5)
Rotate two or three shifts	15.8	19	(5.5, 60.9)
Other	15.2	33	(3.0, 27.5)
Father worked three months before pregnancy			
Yes	9.9	971	(8.0, 11.8)
No	17.6	34	(4.8, 30.4)
Father's occupation			
Electronics worker	20.0	15	(4.3, 48.1)
Health care worker	21.4	14	(4.8, 46.6)

Table 2.12 (Continued)

Variable	SAB Rate (%)	N (Pregnancies)[a]	95% Confidence Interval
First trimester chemical exposure at work or home or in other activity			
None reported	10.3	747	(8.1, 12.5)
Solvents	17.1	76	(8.6, 25.6)
Gasoline	5.6	71	(0.3, 11.0)
Pesticides	13.0	23	(2.8, 33.0)
Pest control work done at residence during first trimester			
Yes	10.0	40	(0.7, 19.3)
No	10.1	943	(8.2, 12.0)
Exposure during three months before pregnancy began or first trimester to:			
Video display terminals			
Yes	11.3	204	(7.0, 15.6)
No	10.0	803	(7.9, 12.1)
Chest x-ray			
Yes	15.8	19	(3.4, 38.0)
No	10.0	974	(8.1, 11.9)

Variable	SAB Rate (%)	N (Pregnancies)[a]	95% Confidence Interval
Pelvic x-ray			
Yes	5.6	18	(0.1, 26.7)
No	10.3	984	(8.4, 12.2)
Other x-ray			
Yes	6.2	81	(1.0, 11.5)
No	10.3	915	(8.3, 12.3)
Used water from a private well			
Yes	20.0	5	(0.5, 71.6)
No	10.1	994	(8.2, 12.0)
Water filter use around time pregnancy began			
Yes	4.5	67	(0.0, 9.5)
No	10.7	926	(8.7, 12.7)
Mother's ethnicity			
White	11.5	755	(9.2, 13.8)
Hispanic	10.9	101	(4.8, 17.0)
Asian	4.2	118	(0.6, 7.8)
Black	0.0	20	(0.0, 13.9)
American Indian	0.0	4	NC
Other	0.0	9	(0.0, 25.0)

Table 2.12 (Continued)

Variable	SAB Rate (%)	N (Pregnancies)[a]	95% Confidence Interval
Mother's education			
0-8 yrs	20.0	10	(2.5, 55.6)
9-11 yrs	10.6	47	(1.8, 19.4)
12 (High School grad)	9.1	309	(5.9, 12.3)
13-15	9.5	347	(6.4, 12.6)
16+ (college grad or more)	11.8	289	(8.1, 15.5)
Father's ethnicity			
White	11.0	737	(8.7, 13.3)
Hispanic	10.6	113	(4.9, 16.3)
Asian	4.5	111	(0.6, 8.4)
Black	4.2	24	(0.1, 20.7)
American Indian	0.0	3	NC
Other	17.7	17	(3.8, 42.4)
Father's education			
0-8 yrs	16.7	12	(2.1, 45.9)
9-11 yrs	10.6	47	(1.8, 19.4)
12 (High School grad)	11.3	212	(7.0, 15.6)
13-15	10.0	321	(6.7, 13.3)
16+ (college grad or more)	9.6	405	(6.7, 12.5)

Table 2.12 (Continued)

Variable	SAB Rate (%)	N (Pregnancies)[a]	95% Confidence Interval
First trimester cold home tap water consumption			
Yes	12.0	775	(9.7, 14.3)
No	3.3	213	(0.9, 5.7)
First trimester cold tap water consumption home or work			
Yes	11.4	837	(9.3, 13.6)
No	4.1	147	(0.9, 7.3)
Bottled water use at home anytime during pregnancy			
Yes	4.8	418	(2.8, 6.9)
No	14.2	586	(11.4, 17.0)
Bottled water use at home or work anytime during pregnancy			
Yes	5.6	480	(3.5, 7.7)
No	14.6	520	(11.6, 17.6)

Table 2.13

Gestational Weeks of Spontaneous Abortions[a] by
Census Tracts and Time Periods

CENSUS TRACT

	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(O)	5120.11(N)	BOTH	5120.08(O)	5053.0204(N)	BOTH	TOTAL
1980 - 1981							
mean	9.8	9.8	9.8	12.6	12.8	12.7	10.9
± std err	± .9	± 1.7		± 2.8	± 2.2		
(N)	(13)	(4)		(5)	(6)		
1982-1985							
mean	12.1	12.3	12.2	9.8	10.4	10.0	11.2
± std err	± .9	± .8		± .9	± .9		
(N)	(22)	(20)		(23)	(10)		
MEANS	11.2	11.9		10.3	11.3		

[a] Among a single random eligible pregnancy per woman.
O = Original study area
N = New study area

P values for comparisons of average gestational weeks are 1) SABs conceived in 1980 or 1981 compared to 1982 - 1985 (p=.80); 2) SABs conceived in 5120.12 versus 5120.11 versus 5120.08 versus 5053.0204 (p=.60); 3) SABs conceived in 1980 or 1981 in 5120.12 or 5120.11 versus 1980 or 1981 in 5120.08 or 5053.0204 versus 1982-85 in 5120.12 or 5120.11 versus 1982-1985 in 5120.08 or 5053.0204 (p=.02)

Table 2.14

Multiple Logistic Model of Risk of Spontaneous Abortion

	OR	95% CI	P
Mother's Age			
<20	2.6	(1.3, 5.6)	0.001
20 - 34	1.0		
35+	2.6	(1.0, 6.3)	
Prior spontaneous fetal loss			
0	1.0		0.10
1	1.6	(0.9, 3.0)	
2+	2.2	(0.9, 5.3)	
Ethnicity			
White or Hispanic	1.0		0.01
Other	0.3	(0.1, 0.8)	
Alcohol consumption			
< 4 drink/week	1.0		
4 + drinks/week	1.4	(0.4, 4.4)	0.60
Smoking			
None	1.0		0.94
≤ 1/2 pack/day	1.1	(0.5, 2.2)	
1 or more packs/day	1.2	(0.4, 3.1)	
Probably solvent exposed job			
No	1.0		
Yes	4.8	(1.5, 15.5)	0.008
Home cold tap water and water filter use			
No tap water, no filter	1.0		0.002
No tap water, filter used	4.2	(0.4, 44.3)	
Tap water, no filter	5.5	(2.1, 14.0)	
Tap water, filter	1.6	(0.3, 8.6)	

Table 2.14 (Continued)

	OR	95% CI	P
Census tract & time period			
Original exposed 1980-81	1.0		0.02
Original exposed 1982-85	0.9	(0.4, 1.9)	
New exposed 1980-81	0.2	(0.04, 0.6)	
New exposed 1982-85	0.5	(0.2, 1.2)	
Original control 1980-81	0.2	(0.06, 0.7)	
Original control 1982-85	0.7	(0.3, 1.6)	
New control 1980-81	0.9	(0.3, 2.7)	
New control 1982-85	0.4	(0.1, 1.0)	
Original areas			
Exposed/unexposed 1980-81	5.0		
Exposed/unexposed 1982-85	1.2		
New areas			
Exposed/unexposed 1980-81	0.2		
Exposed/unexposed 1982-85	1.4		

Table 2.15

Validation of Reported Birth Defects

Validation Categories:	N(Defects)	% Distribution
California Birth Defects Monitoring Program (CBDMP) Reportable Defect	37	32
(Malformation)	(36)	
(Deformation)	(1)	
CBDMP Non-Reportable Defect	33	28
Not a defect	45	39
Not validatable	1	1
TOTAL	116	100

Table 2.16

Congenital Anomalies Reported by
Respondent and Validated by
Medical Record or Physician's Report

Old Unexposed Census Tract (5120.08)

Malformation	Month and Year of Birth
One set of toes shorter, toes aren't separated on that foot	01/80
Coloboma of right eye	10/80
Hypospadias	10/80
Low set nasal bridge, tricuspid regurgitation patent foramen ovale	03/82
Pyloric stenosis	07/83
Persistent hypoplastic vitrins with overt microphalmic of right eye	07/83
Pyloric stenosis	04/84

Table 2.16 (Continued)

New Exposed Census Tract (5120.11)

Malformation	Month and Year of Birth
No palpable testes	03/80
Accessory left nipple	09/80
Pectus excavatum	07/82
Double collecting system of left kidney	09/82
Synostosis	01/83
Pyloric stenosis	03/83
Congenital abscense of fibula	08/83
Axial congenital lens opacity at anterior subcapsular region	10/84
Branchial cleft cyst	11/84
Bony abnormality of medial side of right foot	02/85
Deformation	Month and Year of Birth
Facial asymetry	02/85

Table 2.16 (Continued)

Old Exposed Census Tract (5120.12)

Malformation	Month and Year of Birth
Midline fistula	05/80
Two toes on both feet webbed	07/80
Cerebal palsy with hypotonia, significant developmental delay, persistent microcephaly, omphalocele, congenital club foot with deformity of right side	07/80
Talipis equinovous appearance, asymetrical chest wall, elongated ears, pectus carinatum	08/80
Tricuspid atresia, atrial septal defect with right to left shunt and CHF, ventricular septal defect, asymetrical simian crease on left hand	02/81
Bilateral hypoplasia of lung, hypoplasia of left kidney, hypoplasia of left testis, polycystic kidney, absent anus	03/81
Duplication of ureters	09/81
Cleft lip	09/81
Undescended testicle	12/81
Cleft palate, Robin anomaly	12/81
Congenital anal agenesis	11/83
Hypospadias	02/84
Pyloric stenosis	05/84
Two sets of webbed toes, an extra toe on left foot	03/85

Table 2.16 (Continued)

Malformation	Month and Year of Birth
Total anomalous pulmonary venus connection to right atrium	02/85

Deformation	Month and Year of Birth
Clubbed foot	05/80

New Unexposed Census Tract (5053.0204)

Malformation	Month and Year of Birth
Pectus excavatum	03/81
Hypospadias (primary)	09/82
Cleft lip	05/83
Left hydronephroses, left hydroureter,ureterovesico junction obstruct, left ureteral achalasia	05/84

Deformation	Month and Year of Birth
Congenital dislocation of right hip	10/82

Table 2.17

Number of Reportable Malformations Among Singleton Live Births by Census Tract and Year

CENSUS TRACT

TIME PERIOD	EXPOSED			UNEXPOSED			
	5120.12(O)	5120.11(N)	(BOTH)	5120.08(O)	5053.0204(N)	BOTH	TOTAL
Exposed:							
1980	4	2	(6)	3	0	(3)	9
1981	6	0	(6)	0	1	(1)	7
(1980-81)	(10)	(2)	(12)	(3)	(1)	(4)	(16)
Unexposed:							
1982	0	2	(2)	1	1	(2)	4
1983	1	3	(4)	2	1	(3)	7
1984	2	2	(4)	1	1	(2)	6
1985	2	1	(3)	0	0	(0)	3
(1982-85)	(5)	(8)	(13)	(4)	(3)	(7)	(20)
TOTAL	15	10	(25)	7	4	(11)	36

O = Original study area
N = New study area

Table 2.18

Number of Singleton Live Births by Census Tract and Year

CENSUS TRACT

	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(O)	5120.11(N)	(BOTH)	5120.08(O)	5053.0204(N)	BOTH	TOTAL
Exposed:							
1980	52	45	(97)	62	25	(87)	184
1981	44	60	(104)	63	28	(91)	195
(1980-81)	(96)	(105)	(201)	(125)	(53)	(178)	(379)
Unexposed:							
1982	59	69	(124)	42	45	(87)	211
1983	56	62	(118)	71	48	(119)	237
1984	62	97	(159)	70	57	(127)	286
1985	25	17	(42)	26	14	(40)	82
(1982-85)	(202)	(241)	(443)	(209)	(164)	(373)	(816)
TOTAL	298	346	(644)	334	217	(551)	1195

O = Original study area
N = New study area

Table 2.19

Reportable Malformation Rates by Census Tract and Year

CENSUS TRACT

TIME PERIOD	EXPOSED 5120.12(O)	5120.11(N)	(BOTH)	UNEXPOSED 5120.08(O)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	7.7	4.4	(6.2)	4.8	0.0	(3.4)	4.9
1981	13.6	0.0	(5.8)	0.0	3.6	(1.1)	3.6
(1980-81)	(10.4)	(1.9)	(6.0)	(2.4)	(1.9)	(2.2)	(4.2)
Unexposed:							
1982	0.0	3.1	(1.6)	2.4	2.2	(2.3)	1.9
1983	1.8	4.8	(3.4)	2.8	2.1	(2.5)	3.0
1984	3.2	2.1	(2.5)	1.4	1.8	(1.6)	2.1
1985	8.0	5.9	7.1	0.0	0.0	(0.0)	3.7
(1982-85)	(2.5)	(3.3)	(2.9)	(1.9)	(1.8)	(1.9)	(2.5)
TOTAL	5.0	2.9	(3.9)	2.1	1.8	(2.0)	3.0

O = Original study area
N = New study area

Table 2.20

Odds Ratios[a] and 95% Confidence Intervals for Reportable Malformations in Exposed vs. Unexposed Areas by Time Period

	ORIGINAL STUDY AREAS (5120.12/5120.08)		NEW STUDY AREAS (5120.11/5053.0204)	
	OR	95% CI	OR	95% CI
Time period				
1980-81	4.3	(1.2, 14.7)	0.9	(0.1, 6.6)
1982-85	1.2	(0.4, 4.5)	1.7	(0.5, 5.9)

[a]Small sample adjustment

Table 2.21

Congenital Anomaly Rates for Live Births by Condition:
Residents of Santa Clara County Study Areas (1980-1985)
(Rates per 1,000 Live Births)

Condition (ICD-9-CM) (Code)	Number	Study Area Rate[a]	S.F. Bay Area Rate[b]	Atlanta Rate[c]
Anencephaly (no brain) (740)	0	---	0.2	0.5
Spina bifida (741)	0	---	0.4	0.7
Microcephalus (small head) (742.1)	1	0.8	0.9	0.6
Hydrocephalus (742.3)	0	---	0.4	1.2
Anophthalmia (743.0)	0	---	0.1	0.1
Microphthalmia (small eyes) (743.1)	1	0.8	0.2	0.1
Glaucoma (743.2)	0	---	0.1	0.1
Congenital cataract (743.30-34)	1	0.8	0.2	0.3
Ear defects w/deafness (744.0, 744.23) (includes microtia)	0	---	0.3	0.2
Single ventricle (heart) (745.3)	0	---	0.1	0.1
Endocardial cushion defect (745.6)	0	---	0.4	0.4
Pulmonic valve atresia (746.0)	0	---	0.3	0.1
Pulmonic valve stenosis /insufficiency(746.01,746.02)	0	---		
	0	---	0.2	0.2
Aortic valve stenosis /insufficiency(746.3,746.4)	0	---		
	0	---	0.1	0.3
Mitral valve stenosis /insufficiency (746.5,746.4)	0	---	0.1	0.2
Common truncus (745.0)	0	---	0.2	0.1
Transposition of great vessels (745.1)	0	---	0.7	0.4

Table 2.21 (Continued)

Condition (ICD-9-CM) (Code)	Number	Study Area Rate[a]	S.F. Bay Area Rate[b]	Atlanta Rate[c]
Tetralogy of fallot (745.2)	0	---	0.4	0.4
Hypoplastic left heart (746.7)	0	---	0.4	0.3
Congenital heart block (746.86)	0	---	0.1	<0.1
Coarctation of the aorta (747.1)	0	---	0.5	0.4
Anomalous pulmonary venous return (747.41,747.42)	1	0.8	0.2	0.1
Choanal atresia (748.0)	0	---	0.1	0.1
Anomalies of larynx, trachea, bronchus, (748.2,748.3)	0	---	0.1	0.1
Absent,small,cystic lung (748.4,748.5)	1	0.8	0.5	0.7
Cleft palate alone (749.0)	0	---	0.8	0.5
Cleft lip alone (749.1)	2	1.7	0.5	0.4
Cleft lip and cleft palate (749.2)	0	---	0.5	0.7
T-E Fistula, atresia, stenosis (750.3)	0	---	0.3	0.3
Pyloric stenosis (750.5)	4	3.3	2.3	1.2
Atresia/stenosis-small intestine (751.1)	0	---	0.1	0.3
Atresia/stenosis-large intestine, anus (751.2)	2	1.7	0.4	0.4
Hirschsprung's disease (751.3)	1	0.8	0.1	0.2
Biliary atresia (751.61)	0	---	0.1	0.1

Table 2.21 (Continued)

Condition (ICD-9-CM) (Code)	Number	Study Area Rate[a]	S.F. Bay Area Rate[b]	Atlanta Rate[c]
Hypospadias/epispadias (752.6)	3	2.5	3.0	2.9
Indeterminate sex (752.7)	0	---	0.2	0.2
Renal agenesis/dysgenesis (753.0)	1	0.8	0.4	0.4
Cystic kidney disease (753.1)	1	0.8	0.3	0.3
Exstrophy of urinary bladder (753.5)	0	---	0.1	<0.1
Scoliosis, lorsosis of spine (754.2)	0	---	0.6	0.1
Congenital dislocation of hip (754.30, 754.31, 754.35)	1	0.8	1.2	0.7
Clubfoot (754.50, 754.51, 754.53, 754.60, 754.73)	2	1.7	1.7	2.3
Extra thumb, great toe-preaxial polydactyly (755.01, 755.03)	0	---	0.3	0.2
Syndactyly (webbing digits) (755.1)	2	1.7	0.8	0.9
Chondrodystrophies (756.4)	0	---	0.1	0.1
Osteodystrophies (756.5)	1	0.8	0.2	0.1
Diaphragmatic hernia (756.6)	0	---	0.3	0.3
Omphalocele/gastroschisis (756.70,756.71)	1	0.8	0.2	0.6

Table 2.21 (Continued)

Condition (ICD-9-CM) (Code)	Number	Study Area Rate[a]	S.F. Bay Area Rate[b]	Atlanta Rate[c]
Down's syndrome (758.0)	0	---	0.9	1.1
Other autosomal anomalies (758.1, 758.2, 758.3, 758.5)	0	---	0.3	0.4
Sex chromosome anomalies (758.5, 758.7, 758.8)	0	---	0.1	0.1
Congenital viral infection (771.0, 771.1, 771.2)	0	---	0.3	0.1

[a]Total number of live births in study area = 1196.

[b]Five San Francisco Bay Area counties January 1, 1983-June 30, 1983.

[c]1979-1983

Source: Report of the California Birth Defects Monitoring Program, Congenital Malformations Among Live Births, January 1, 1983, - June 30, 1983, Berkeley, California.

Table 2.22
Listing of Congenital Malformations Occuring In More Than Two Children and Maternal Risk Factors

Congenital Malformation (ICD-9-CM)	Exposed census tracts	Age of mother at birth < 20 or > 35	Chemical[a] exposure at work or home	Home pest-[a] control	Use of [a] tap water filter	VDT[a] use	Cigarette[a] smoking
Pyloric stenosis (750.5)							
case #1	no	no	no	yes	no	yes	yes
case #2	no	no	no	yes	no	no	yes
case #3	yes	yes	yes	no	no	yes	no
case #4	yes	no	no	no	no	no	no
Anomalies of genitourinary system (751.2, 751.3)							
case #1	yes	no	no	yes	no	no	no
case #2	yes	no	no	no	yes	no	no
case #3	no	no	no	no	no	yes	yes
Hypospadias (752.6)							
case #1	no	no	no	no	no	no	no
case #2	yes	no	no	no	no	no	no
case #3	no	no	no	yes	no	yes	no
Syndactyly and other malformations of feet (754.7)							
case #1	no	no	no	yes	no	no	yes
case #2	yes	yes	no	no	no	no	no
case #3	yes	no	no	no	no	no	no
case #4	yes	yes	no	no	no	no	no

*None of these women reported the following possible risk factors: diabetes, hypertension, eclampsia, seizures, fever, exposure to X-rays the three months prior to or during pregnancy, or a private well as their source of drinking water.

Table 2.22 (Continued)

Congenital Malformation (ICD-9-CM)	Alcohol[a] consumption	Prescription[a] medication other than prenatal vitamins	Nausea[a]	Amniocentesis	Bleeding	C-section	Family history of congenital malformations
Pyloric stenosis (750.5)							
case #1	yes	no	no	no	no	no	no
case #2	no	no	yes	no	no	no	no
case #3	no	yes	yes	yes	no	yes	no
case #4	no	no	yes	no	no	yes	no
Anomalies of genitourinary system (751.2, 751.3)							
case #1	yes	no	yes	no	no	yes	no
case #2	no	yes	no	no	no	no	no
case #3	yes	no	no	no	yes	yes	no
Hypospadias (752.6)							
case #1	no	no	no	no	no	no	no
case #2	no	no	yes	no	no	no	no
case #3	yes	no	no	no	no	no	no
Syndactyly and other malformations of feet (754.7)							
case #1	no	yes	yes	no	no	no	no
case #2	no	no	no	no	no	no	yes
case #3	no	no	no	no	no	yes	no
case #4	no	no	yes	no	no	no	no

[a]First trimester exposure

Table 2.23

Number of Low Birth Weight Babies among All Births Reported on Birth Certificates

CENSUS TRACT

	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(0)	5120.11(N)	(BOTH)	5120.08(0)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	4	5	(9)	4	2	(6)	15
1981	2	3	(5)	8	1	(9)	14
(1980-81)	(6)	(8)	(14)	(12)	(3)	(15)	(29)
Unexposed:							
1982	3	8	(11)	7	6	(13)	24
1983	4	9	(13)	6	6	(12)	25
1984	3	4	(7)	6	4	(10)	17
1985	2	9	(11)	8	2	(10)	21
(1982-85)	(12)	(30)	(42)	(27)	(18)	(45)	(87)
TOTAL	18	38	(56)	39	21	(60)	116

0 = Original study area
N = New study area

Table 2.24

Number of Singleton Live Birth Among All Births Reported on Birth Certificates

CENSUS TRACT

TIME PERIOD	EXPOSED 5120.12(O)	5120.11(N)	(BOTH)	UNEXPOSED 5120.08(O)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	148	164	(312)	188	115	(303)	615
1981	133	130	(263)	184	89	(273)	536
(1980-81)	(281)	(294)	(575)	(372)	(204)	(576)	(1151)
Unexposed:							
1982	107	179	(286)	169	101	(270)	556
1983	131	130	(261)	172	119	(291)	552
1984	121	151	(272)	149	122	(271)	543
1985	117	168	(285)	174	119	(293)	578
(1982-85)	(476)	(628)	(1104)	(664)	(461)	(1125)	(2229)
TOTAL	757	922	(1679)	1036	665	(1701)	3380

O - Original study area
N - New study area

1597.tb3/9

Table 2.25

Low Birth Weight Rates Among All Births Reported on Birth Certificates

CENSUS TRACT

	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(O)	5120.11(N)	(BOTH)	5120.08(O)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	2.7	3.1	(2.9)	2.1	1.7	(2.0)	2.4
1981	1.5	2.3	(1.9)	4.4	1.1	(3.3)	2.6
(1980-81)	(2.1)	(2.7)	(2.4)	(3.2)	(1.5)	(2.6)	(2.5)
Unexposed:							
1982	2.8	4.5	(3.8)	4.1	5.9	(4.8)	4.3
1983	3.1	6.9	(4.9)	3.5	5.0	(4.1)	4.5
1984	2.5	2.7	(2.6)	4.0	3.3	(3.7)	3.1
1985	1.7	5.4	(3.9)	4.6	1.7	(3.4)	2.4
(1982-85)	(2.5)	(4.8)	(3.8)	(4.1)	(3.9)	(4.0)	(3.9)
TOTAL	2.4	4.1	(3.3)	3.8	3.2	(3.5)	3.4

O = Original study area
N = New study area

1597.tbl/9

Table 2.26

Odds Ratios and 95% Confidence Intervals for Low Birth Weight in Exposed vs. Unexposed Areas by Time Period Among All Births Reported on Birth Certificates

	ORIGINAL STUDY AREAS (5120.12/5120.08)		NEW STUDY AREAS (5120.11/5053.0204)	
	OR	95% CI	OR	95% CI
Time period				
1980-81	0.7	(0.2, 1.8)	1.7[a]	(0.5, 6.0)
1982-85	0.6	(0.3, 1.2)	1.2	(0.7, 2.2)

[a]Small sample adjustment

Table 2.27

Number of Low Birth Weight Babies by Census Tract and Year Among Interviewed Women[a]

CENSUS TRACT

	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(0)	5120.11(N)	(BOTH)	5120.08(0)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	0	1	(1)	3	0	(3)	4
1981	1	3	(4)	3	0	(3)	7
(1980-81)	(1)	(4)	(5)	(6)	(0)	(6)	(11)
Unexposed:							
1982	1	1	(2)	0	2	(2)	4
1983	1	1	(2)	2	2	(4)	6
1984	1	4	(5)	3	1	(4)	9
1985	0	1	(1)	0	0	(0)	1
(1982-85)	(3)	(7)	(10)	(5)	(5)	(10)	(20)
TOTAL	4	11	(15)	11	5	(16)	31

[a] Based on a single random eligible pregnancy per woman.
0 = Original study area
N = New study area

1597.tb7/9

Table 2.28

Number of Singleton Live Births With Known Birth Weight by Census Tract and Year Among Interviewed Women[a]

	CENSUS TRACT						
	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(O)	5120.11(N)	(BOTH)	5120.08(O)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	42	33	(75)	52	16	(68)	143
1981	32	48	(80)	51	21	(72)	152
(1980-81)	(74)	(81)	(155)	(103)	(37)	(140)	(295)
Unexposed:							
1982	43	54	(97)	32	30	(62)	159
1983	42	47	(89)	57	37	(94)	183
1984	52	77	(129)	55	47	(102)	231
1985	16	14	(30)	18	10	(28)	58
(1982-85)	(153)	(192)	(345)	(162)	(124)	(286)	(631)
TOTAL	227	273	(500)	265	161	(426)	926

[a] Based on a single random eligible pregnancy per woman.
O = Original study area
N = New study area

Table 2.29

Low Birth Weight Rates by Census Tract and Year Among Interviewed Women[a]

CENSUS TRACT

	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(O)	5120.11(N)	(BOTH)	5120.08(O)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	0.0	3.0	(1.3)	5.8	0.0	(4.4)	2.8
1981	3.1	6.3	(5.0)	5.9	0.0	(4.2)	4.6
(1980-81)	(1.4)	(4.9)	(3.2)	(5.8)	(0.0)	(4.3)	(3.7)
Unexposed:							
1982	2.3	1.9	(2.1)	0.0	6.7	(3.2)	2.5
1983	2.4	2.1	(2.3)	3.5	5.4	(4.3)	3.3
1984	1.9	5.2	(3.9)	5.5	2.1	(3.9)	3.9
1985	0.0	7.1	(3.3)	0.0	0.0	(0.0)	1.7
(1982-85)	(2.0)	(3.7)	(2.9)	(3.1)	(4.0)	(3.5)	(3.2)
TOTAL	1.8	4.0	(3.0)	4.2	3.1	(3.8)	3.3

[a] Based on a single random eligible pregnancy per women.
O = Original study area
N = New study area

Table 2.30

Odds Ratios[a] and 95% Confidence Intervals for Low Birth Weight in Exposed vs. Unexposed Areas by Time Period Among Interviewed Women

	ORIGINAL STUDY AREAS (5120.12/5120.08)		NEW STUDY AREAS (5120.11/5053.0204)	
	OR	95% CI	OR	95% CI
Time period				
1980-81	0.3	(0.05, 1.9)	4.4	(0.2, 83.0)
1982-85	0.7	(0.2, 2.6)	0.9	(0.3, 2.9)

Source: SCC12

[a]Small sample adjustment

1597.tb5/9

Table 2.31A

Comparisons of Mean Estimated Cumulative TCA (ppb) Exposure Among Women with Pregnancies[a] Ending in Live Birth and Those Ending in Spontaneous Abortion

	All Pregnancies Per Woman				Random Eligible Pregnancy[b]			
	N	1st month of pregnancy	1st, 2nd month	1st, 2nd & 3rd month	N	1st month of pregnancy	1st, 2nd month	1st, 2nd & 3rd month
Live Births	104	1052	2119	3202	80	904	1809	2797
All Reported SABs	25	1057	1960	2749	16	1002	2063	3098
(mean square error)		(1296212)	(4904497)	(9862612)		(1428763)	(5580761)	(11791667)
p(ANOVA)		.98	.75	.52		.76	.70	.75
p(WILCOXON)		.60	.56	.43		.23	.32	.33
Definite SAB's	20	824	1681	2469	12	928	1996	3044
(mean square error)		(1196151)	(4784766)	(9660986)		(1467716)	(5742787)	(12100605)
p(ANOVA)		.39	.41	.33		.95	.80	.82
p(WILCOXON)		.27	.36	.35		.47	.48	.48

[a] Includes pregnancies with estimated dates of conception in 1981 in census tracts 5120.11 and 5120.12.

[b] Zero exposure for women reporting water filter use or no cold home tap water consumption.

1595.tbl/3

Table 2.31B

Percent Distributions of Spontaneous Abortions[a] And Live Births[b] by Quartiles of Estimated TCA (ppb) Exposure

CT 5120.11 TCA (ppb) 1st month	Definite SABs No.	(%)	Live births No.	(%)	All SABs No.	(%)	Live births No.	(%)
0- 199	1	(6)	16	(94)	2	(11)	16	(89)
200- 899	3	(18)	14	(82)	3	(18)	14	(82)
900-2199	1	(6)	15	(94)	1	(6)	15	(94)
2206+	1	(6)	15	(94)	4	(21)	15	(79)
TOTAL	6		60		10		60	

CT 5120.12 TCA (ppb) 1st month	Definite SABs No.	(%)	Live births No.	(%)	All SABs No.	(%)	Live births No.	(%)
0-42.99	5	(42)	7	(58)	5	(42)	7	(58)
43-399.99	3	(23)	10	(77)	4	(28)	10	(71)
400-1259.99	2	(17)	10	(83)	2	(16)	10	(83)
1260+	4	(27)	11	(73)	4	(27)	11	(73)
TOTAL	14		38		15		38	

[a]Uses all eligible pregnancies per woman in 1981.

[b]Live births minus six infants with birth defects.

Table 2.32

Comparisons of Mean Estimated Probability of Exposure to Water from Well #13 Among Women with Pregnancies[a] Ending in Live Birth and Those Ending in Spontaneous Abortion (SAB)

	All Pregnancies Per Woman				Random Eligible Pregnancy[b]			
	N	1st Month of Pregnancy	Maximum of 1st, 2nd Month	Maximum of 1st, 2nd & 3rd Month	N	1st month of Pregnancy	Maximum of 1st, 2nd Month	Maximum of 1st, 2nd & 3rd Month
Live Births	104	.40	.45	.48	80	.37	.41	.45
All Reported SABs	25	.42	.46	.47	16	.42	.47	.49
(mean square error)		(.06)	(.06)	(.06)		(.08)	(.08)	(.09)
p(ANOVA)		.67	.84	.90		.52	.51	.59
p(WILCOXON)		.83	.83	.98		.38	.43	.70
vs. Definite SAB's	20	.38	.44	.45	12	.40	.46	.49
(mean square error)		(.06)	(.06)	(.06)		(.09)	(.09)	(.09)
p(ANOVA)		.81	.77	.59		.72	.60	.64
p(WILCOXON)		.63	.69	.54		.59	.49	.70

[a] Includes pregnancies with estimated dates of conception in 1981 in census tracts 5120.11 and 5120.12.

[b] Zero exposure for women reporting water filter use or no cold home tap water.

Table 2.33

Comparisons of Mean Estimated Cumulative Probability of No Exposure to Water from Well #13 Among Women with Pregnancies Ending in Live Birth and Those Ending in Spontaneous Abortion (SAB)[a]

	All Pregnancies Per Woman				Random Eligible Pregnancy[b]			
	N	1st month of pregnancy	1st, 2nd month	1st, 2nd & 3rd month	N	1st month of pregnancy	1st, 2nd month	1st, 2nd & 3rd month
Live Births	104	.60	.43	.33	80	.63	.50	.41
All reported SABs	25	.58	.44	.36	16	.58	.42	.31
(mean square error)		(.06)	(.07)	(.08)		(.08)	(.11)	(.14)
p (ANOVA)		.67	.87	.66		.52	.39	.29
p (WILCOXON)		.84	.76	.50		.38	.47	.59
Definite SABs	20	.60	.45	.36	12	.60	.43	.31
(mean square error)		(.06)	(.07)	(.08)		(.09)	(.11)	(.14)
p (ANOVA)		.81	.68	.67		.72	.53	.39
p (WILCOXON)		.63	.46	.44		.59	.56	.61

[a]Includes pregnancies with estimated dates of conception in 1981 in census tracts 5120.11 and 5120.12.

[b]Zero exposure for women reporting water filter use or no cold home tap water consumption.

Table 2.34

Comparisons of Mean Cumulative TCA (ppb) Exposure to Women with Pregnancies[a] Resulting in Normal Live Births or in Live Births with Malformation

	N	1st month	1st, 2nd month	1st, 2nd & 3rd month
Live Births with No Defects	98	1091	2204	3334
Live Births with CBDMP[b] Reportable Malformations	6	419	758	1063
(mean square error)		(1206735)	(4855557)	(10138658)
p(ANOVA)		.15	.11	.09
p(WILCOXON)		.22	.09	.04

Average Estimated Maximum Probability of Exposure to Water from Well #13

	N	1st month	1st & 2nd month	1st, 2nd & 3rd month
Live Births No Defects	98	.41	.47	.49
Live Births with CBDMP[b] Reportable Malformations	6	.17	.23	.28
(mean square error)		(.06)	(.05)	(.06)
p(ANOVA)		.01	.02	.03
p(WILCOXON)		.01	.04	.07

Average Estimated Cumulative Probability of No Exposure to Water from Well #13

	N	1st month	1st & 2nd month	1st, 2nd & 3rd month
Live Births No Defects	98	.59	.41	.31
Live Births with CBDMP[b] Reportable Malformations	6	.83	.71	.62
(mean square error)		(.06)	(.07)	(.08)
p(ANOVA)		.01	.008	.009
p(WILCOXON)		.01	.03	.02

[a]Includes all reported live births conceived in 1981 in census tracts 5120.11 and 5120.12.

[b]California Birth Defects Monitoring Program

Enumeration Cover Letter

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY GEORGE DEUKMEJIAN, Governor

DEPARTMENT OF HEALTH SERVICES
2151 BERKELEY WAY
BERKELEY, CA 94704

Dear Resident:

We are conducting an important health study in Santa Clara County. In 1981, a leak of potentially dangerous chemicals into a well of the Great Oaks Water Company was discovered. The contaminated well was promptly closed. In response to community concern about possible health effects of the leak, state and county researchers studied birth defects and miscarriages in an area of San Jose that may have received the contaminated water and in a similar neighborhood with a different source of water. More birth defects and miscarriages occurred in 1980 and 1981 in the area that may have received the contaminated water.

Because we do not know when the leak began, we could not conclude that the contaminated water was responsible for the problems. We do know the contaminated well was closed in December of 1981. Therefore, we are expanding the original study to see if the higher rates of birth defects and miscarriages continued after the contamination stopped. This study also will include two new neighborhoods in addition to the two previously studied areas.

WE NEED YOUR HELP TO CONDUCT THE NEW STUDY. We need a list of all the individuals residing at this address. We also need to know whether any of the women in the household were pregnant at any time during the six year period from January 1, 1980 through December 31, 1985. We are interested in all pregnancies regardless of whether they ended with a live birth, stillbirth, miscarriage or abortion. We will contact women who have been pregnant during the study period and ask them to participate in an interview.

Please have an adult woman living at this address fill out the enclosed form. It does not matter whether she has ever been pregnant. An adult man may complete the form if there are no adult women in the household. We need to receive a form from your household WHETHER OR NOT THERE ARE ANY WOMEN in the household. We also need this information now even though you may have filled out a form like this in the past.

All information on these forms will be kept confidential as required by the State Health and Safety Code and will be used only for this study. No individuals or families will be identifiable in any analysis or report. If you have any questions, please call Kathleen Claxton or Margaret Wrensch at (415) 540-2669.

Thank you for reading this letter and for taking the time to return the form to us. A pre-addressed, stamped envelope is enclosed.

Sincerely,

Margaret Wrensch

Margaret Wrensch, Ph.D.
Epidemiologist
Department of Health Services
State of California

Stephan Coray, M.D.

Stephan Coray, M.D.
Chief of Health Protection
Santa Clara County Health Deparment
408/299-5858

Enumeration Form

Please have an adult woman who lives at this address complete this form. If there are no adult women in the household, then an adult man may complete the form. Please list each person in your household. LIST YOURSELF FIRST then each member of your household, including infants. Start with the oldest person, then list the next oldest, etc.

INCLUDE ANYONE WHO lives here or is staying here and has no other home, whether related to you or not; has a home elsewhere but who stays here most of the time; lives here but is away temporarily. DO NOT INCLUDE people currently away in the armed forces; college students currently home only weekends or less; or people currently away from home in institutions.

Please Print

First Name	Middle Initial	Last Name	Birthdate MO	DAY	YR	Sex M/F	For each female born before 1970, was she ever pregnant anytime in 1980-85? (We are interested in all pregnancies including live births, stillbirths, miscarriages and abortions.). Please Check Yes or No. YES	NO
Your name:								
Household members:								

(Continue on back if necessary.)

In case we need more information, what is your:

home phone number ______________ work phone number ______________

What is the best time to reach you? ______________ a.m. / p.m.

When did you move to this address? ______________ month year

Please give us the name, address and telephone number of a relative, friend, or organization who would be apt to know how we can reach you, if you move away.

Name | Address | Phone Number

THANK YOU

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY GEORGE DEUKMEJIAN, Governor

DEPARTMENT OF HEALTH SERVICES
2151 BERKELEY WAY
BERKELEY, CA 94704

415/540-2669

We recently received the form from your household in response to the first phase of our health study. Thank you for your cooperation in returning that information to us. The form indicated that you were pregnant sometime between 1980 and 1985. We now would like to interview you concerning your pregnancies.

The interview is usually conducted by telephone. Your participation in the interview is entirely voluntary, and you may terminate the interview at any time. All information received during the interview will be kept confidential as required by the State Health and Safety Code. It will be used only in statistical summaries and no individuals will be identified in any analysis or report. An interviewer will telephone you within the next few weeks to answer any questions you may have and to schedule an interview.

As we explained in the previous letter, this study is an extension of a recent study of miscarriages and birth defects in Santa Clara County. The original study showed that in 1980 and 1981 more birth defects and miscarriages occurred in an area of San Jose served by the Great Oaks Water Company than in a similar neighborhood with a different source of water. This new study will cover 1980 to 1985 and will add two neighborhoods to those originally studied. This study will help to clarify the reasons for the previously observed excess of miscarriages and birth defects and will tell us whether this excess still persists.

To obtain useful information, a high proportion of the women living in all the study areas who were pregnant anytime between 1980 and 1985 must participate. We hope you will participate. If you have any questions please write or call us.

We greatly appreciate your help in this study.

Sincerely,

Margaret Wrensch

Margaret Wrensch, Ph.D.
Epidemiologist
Epidemiological Studies and
Surveillance Section

Stephan Coray

Stephan Coray, M.D.
Chief of Health Protection
Santa Clara Co. Health Dept.
408/299-5858

1512.5

Cover Letter Requesting Permission to Contact Physician About Reported Spontaneous Abortion

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY GEORGE DEUKMEJIAN, Governor

DEPARTMENT OF HEALTH SERVICES
2151 BERKELEY WAY
BERKELEY, CA 94704

415/540-2669

Dear

In a recent interview you reported having a miscarriage in .
As the interviewer mentioned, we would like your permission to contact your physician for more medical information.

Please check the enclosed consent form to see that the date and doctor's name and address are correct. Please fill in any missing information; then sign the form and return it in the enclosed stamped, self-addressed envelope.

Thank you again for your help in this study.

Sincerely,

D. Shusterman

Dennis Shusterman, MD, MPH
Medical Epidemiologist
Epidemiological Studies and
Surveillance Section

Permission Form to Contact Physician About Reported Spontaneous Abortion

STUDY ID _ _ _ _ _ _ _

DATE OF MISCARRIAGE (SPONTANEOUS ABORTION): ____________________

NAME OF DOCTOR: ______________________________________

ADDRESS: ______________________________________

____

____

The California State Department of Health Services has my permission to obtain information concerning my miscarriage (spontaneous abortion) occurring on the date given above.

SIGNED: ______________________________________

1513/rls.5

Spontaneous Abortion Validation Form

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY GEORGE DEUKMEJIAN, Governor

DEPARTMENT OF HEALTH SERVICES
2151 BERKELEY WAY
BERKELEY, CA 94704
415/540-2669

Dear

During our study of pregnancy outcomes in Santa Clara County, stated that she had had a miscarriage in . Enclosed is an authorization form for you to release information concerning this miscarriage.

To verify the diagnosis and complete our study we would like the following information:

Was the reported miscarriage a spontaneous abortion (less than 20 weeks gestation)?

[ ] YES [ ] NO

If "yes," what was the cause of, or the circumstances surrounding, the reported miscarriage?

____

____

____

If "no," please describe what happened. If it was an induced abortion, was it performed because of known or suspected fetal abnormalities?

____

____

Please return this to us as soon as possible in the enclosed stamped self-addressed envelope.

Your cooperation is greatly appreciated.

Sincerely,

D. Shusterman

Dennis Shusterman, M.D., M.P.H.
Epidemiological Studies Section

1514.5

Cover Letter Requesting Permission to Contact
Physician About Reported Birth Defect

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY GEORGE DEUKMEJIAN, Governor

DEPARTMENT OF HEALTH SERVICES
2151 BERKELEY WAY
BERKELEY, CA 94704

415/540-2669

Dear

In a recent interview you reported that your child was diagnosed as having a birth defect. As the interviewer mentioned, we would like your permission to contact the physician who made the diagnosis for more medical information.

Please check the enclosed consent form to see that the child's name, and the doctor's name and address are correct. Please fill in any missing information; then sign the form and return it in the enclosed stamped, self-addressed envelope.

Thank you again for your help in this study.

Sincerely,

D. Shusterman

Dennis Shusterman, MD, MPH
Medical Epidemiologist
Epidemiological Studies and
Surveillance Section

1515.5

Permission Form to Contact Physician
About Reported Birth Defect

STUDY ID ___ ___ ___ ___ ___ ___ ___

CHILD'S NAME: ______________________________

APPROXIMATE DATE OF DIAGNOSIS: ______________________________

BIRTH DEFECT DIAGNOSED: ______________________________

____

____

NAME OF DOCTOR: ______________________________

ADDRESS: ______________________________

The California State Department of Health Services has my permission to obtain information about the birth defects my child has.

SIGNED: ______________________________

1515/r1.5

Birth Defect Validation Form

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY GEORGE DEUKMEJIAN Governor

DEPARTMENT OF HEALTH SERVICES
2151 BERKELEY WAY
BERKELEY, CA 94704
415/540-2669

Dear

During our study of pregnancy outcomes in Santa Clara County, stated that you had diagnosed birth defect(s) in her child Enclosed is an authorization form for you to release information concerning the birth defect(s).

To verify the diagnosis and complete our study please record the conditions you have diagnosed in this child.

Date 1st Diagnosed	Condition

Please return this to us as soon as possible in the enclosed stamped self-addressed envelope.

Your cooperation is greatly appreciated.

Sincerely,

D. Shusterman

Dennis Shusterman, M.D., M.P.H.
Epidemiological Studies Section

1516.5

Questionnaire

TIME INTERVIEW STARTED ____________ ID __ __ __ __ __ __ 1/
TOTAL TIME ____________ 7/ CT HH# W#
INTERVIEWER'S INITIALS ____________ 10/ DATE ____________ 13/

PREGNANCY OUTCOME QUESTIONNAIRE

Hello. May I speak to _____. I'm _______ from the California Department of Health Services. I'm interviewing for the health study of women in Santa Clara County who have been pregnant. Did you receive a letter from us concerning this study? PAUSE. [IF NO, READ LETTER OR SEND LETTER IF REQUESTED AND SET A TIME TO CALL BACK.]

I'd like to interview you now if it's convenient. All information you give me is confidential and will be used only in statistical summaries. PAUSE.

IF NOT CONVENIENT TIME FOR INTERVIEW, SET A TIME TO CALL BACK. IF R HESITATES, TRY TO FIND OUT WHY, TO ANSWER ANY OBJECTIONS AND TO PERSUADE THE R TO ALLOW HERSELF TO BE INTERVIEWED. R MAY CONFIRM THE LEGITIMACY OF THE STUDY BY PHONING DAVID EPSTEIN COLLECT AT (415) 540-2934. IF R REFUSES DON'T PUSH, LEAVE THE DOOR OPEN FOR SECOND TRY.

1. First of all, what is your birthdate?

   ____ MONTH ____ DAY ____ YEAR 19/

   [ ] DK IF DON'T KNOW: How old are you? _____ 25/

2. Have you ever been pregnant, even if only for a short time? Please include any pregnancy regardless of whether it ended in a live birth, stillbirth, miscarriage, abortion or was an ectopic pregnancy.

   1[ ] YES
   2[ ] NO
   9[ ] DK

   IF NO OR DON'T KNOW, TERMINATE INTERVIEW. 27/
   SAY: Thank you very much for your help in this study. We are only interviewing women who have been pregnant.

3. When did your most recent pregnancy end?

   ____ MONTH ____ YEAR 28/

IF MOST RECENT PREGNANCY ENDED BEFORE JANUARY 1, 1980, TERMINATE INTERVIEW. SAY: We're primarily interested in pregnancies that occurred during or after 1980, so I won't need to ask you anymore questions at this time. Thank you very much for your help in this study.

IF MOST RECENT PREGNANCY ENDED SINCE JAN 1, 1980 GO TO QUESTION 4.

4. Now I would like to ask you some questions to summarize your entire pregnancy history. Let's start with your very first pregnancy. ASK A-E AS APPROPRIATE.

Did you have another pregnancy after this one? IF YES, ASK A-E: IF NO ASK: ASK 4-F

	A	B
CHECK HERE IF TWIN OR MULTIPLE BIRTH.	Did this pregnancy end with a live birth, stillbirth, miscarriage, elective abortion or was it an ectopic pregnancy? PREGNANCIES AFTER THE 1ST: How did this pregnancy end?	IF LIVE BIRTH: Did the baby have any abnormalities or birth defects noticed at birth or within the first 6 months of life?

			OUTCOME					
	LIVE BIRTH	MISCARRIAGE BEFORE 20 WK	STILLBIRTH AFTER 20 WK	ECTOPIC TUBAL	ELECTIVE ABORTION	CURRENTLY PREGNANT	YES	NO
1[ ]	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	1[ ]	2[ ]
1[ ]	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	1[ ]	2[ ]
1[ ]	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	1[ ]	2[ ]
1[ ]	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	1[ ]	2[ ]
1[ ]	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	1[ ]	2[ ]
1[ ]	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	1[ ]	2[ ]
1[ ]	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	1[ ]	2[ ]
1[ ]	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	1[ ]	2[ ]
1[ ]	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	1[ ]	2[ ]
1[ ]	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	1[ ]	2[ ]

4F. AFTER LAST, COUNT PREGNANCIES: I count that you've had a total of _____ (#) pregnancies. Did you have any others that we might have missed? Any which were very short or ended in abortion? IF SO, ADD TO ABOVE. *322/*

4G. WHEN HISTORY COMPLETE: Excuse me a moment. I'm going to mark a calendar with the months you were pregnant between 1980 and 1985 and check whether you were living in our study areas during that pregnancy. I'll then ask you some more detailed questions about those pregnancies. MARK CALENDAR.

C		D			E			
How long did the pregnancy last?		IF LIVE: What was the baby's birthday? OTHERWISE: When did the pregnancy end?			IF BEGAN ON/AFTER 1/1/80 AND ENDED ON/BEFORE 12/31/85 At what address did you live during this pregnancy? Did you live anywhere else during that time?	When did you move in?		CHECK BOX IF ELIGIBLE
MONTHS	WEEKS	MONTH	DAY	YEAR	ADDRESS	MN	YR	ELIGIBLE
___	___	___	___	___		___	___	[ ] 32/
___	___	___	___	___		___	___	[ ] 61/
___	___	___	___	___		___	___	[ ] 90/
___	___	___	___	___		___	___	[ ] 119/
___	___	___	___	___		___	___	[ ] 148/
___	___	___	___	___		___	___	[ ] 177/
___	___	___	___	___		___	___	[ ] 206/
___	___	___	___	___		___	___	[ ] 235/
___	___	___	___	___		___	___	[ ] 264/
___	___	___	___	___		___	___	[ ] 293/

ELIGIBLE IF:

1. **Live birth, stillbirth, miscarriage**
2. **Began on/after 1/1/80**
3. **Ended on/before 12/31/85**
4. **Resident in study area <u>entire</u> time of pregnancy**

IF NO PREGNANCIES BEGAN ON OR AFTER JAN 1, 1980 OR ENDED ON OR BEFORE DEC 31, 1985 **TERMINATE** INTERVIEW AND SAY: We're primarily interested in pregnancies that ended in a live birth, miscarriage or stillbirth and that occurred in the study areas between 1980 and 1985, so I don't need to ask you any more questions at this time. Thank you very much for your help in this study.

OTHERWISE, RESUME THE INTERVIEW WITH THE FIRST ELIGIBLE PREGNANCY.

I've marked a calendar with the months you were pregnant for each pregnancy between 1980 and 1985. I'm going to ask you some questions about each pregnancy that ended with a (live birth, stillbirth or miscarriage) during this time.

CHECK CALENDAR AND GO TO FIRST ELIGIBLE PREGNANCY.

PREG # __1__ of _____ 324/

Let's begin with the pregnancy that ended __________ (MONTH) of _______ (YEAR) and that began around 325/ ______________ (MONTH) of ____________ (YEAR); and that you said resulted in a ________________ (OUTCOME); is that correct? [IF NO, CORRECT DATES AND OUTCOME]

IF THE PREGNANCY ENDED IN A:

TWIN BIRTH, USE TWIN FORM FOR SECOND BABY.
OTHER MULTIPLE BIRTH: USE TWIN FORM FOR OTHER BABIES AND MARK IT "TRIPLETS", "QUADS", ETC.

MISCARRIAGE CONTINUE TO NEXT QUESTION

STILLBIRTH SKIP TO QUESTION 6 ON PAGE 5

LIVE BIRTH SKIP TO QUESTION 7 ON PAGE 6

5. FOR MISCARRIAGES ONLY

a. Did you have a pregnancy test for this pregnancy?

1 [ ] YES: 1. Was the test done: 333/

1 [ ] at home? 334/
2 [ ] at a doctor's office?
3 [ ] at a hospital or clinic?
4 [ ] or at some other place? (DESCRIBE)________________

2. Was the outcome of this test positive?

1 [ ] YES
2 [ ] NO
9 [ ] DK 335/

2 [ ] NO
9 [ ] DK

b. Did you see a physician for this miscarriage?

1 [ ] YES: 1. What was the physician's or clinic's name? 336/

________________________ ________ 337/
PHYSICIAN FIRST NAME LAST OR CLINIC

2. Did you have a D and C for this pregnancy?
1 [ ] YES 2 [ ] NO 338/

2 [ ] NO

SKIP TO QUESTION 8 ON PAGE 8

6. FOR STILLBIRTHS ONLY

a. Did you see a physician or go to a hospital for this stillbirth?

1 [ ] YES: 1. What were the physician's and hospital's names? 339/

________________________ 340/
PHYSICIAN'S FIRST NAME LAST

________________________ 341/
HOSPITAL CITY

2 [ ] NO

SKIP TO QUESTION 8 ON PAGE 8

7. FOR LIVE BIRTHS ONLY

a. Was the baby a boy or a girl? 343/
1 [ ] BOY
2 [ ] GIRL

b. What name appears on the baby's birth certificate?

____ 344/
FIRST MIDDLE LAST

c. Was the baby born in a hospital,clinic or at home?

1[ ] HOSPITAL OR CLINIC: What was the name of the hospital or clinic and what city was it in? 345/

____ 346/
NAME OF HOSPITAL OR CLINIC CITY

2[ ] HOME

d. Let me review this baby's health again: Did the baby have any abnormalities or birth defects noticed at birth or within the first 6 months of life?

1[ ] YES: 1. What did the doctor say the baby's birth defect or abnormality was? PROBE FOR SPECIFIC CONDITION. 349/

______________________________ 350/

____

2. Was this diagnosis made at a hospital or a doctor's office?

1[ ] HOSPITAL: What was the name of the hospital and what city was it in?

______________ HOSPITAL ______________ CITY 351/

What was the doctor's name? ______________ FIRST LAST 353/

2[ ] DOCTOR'S OFFICE: What was the doctor's name?

______________ FIRST LAST 354/

What was (his/her) address?______________ STREET CITY 355/

3. Does any blood relative of the child have this condition?

1[ ] YES: What relationship is the person to the child? 356/

______________________________ 357/

2[ ] NO
9[ ] NOT APPLICABLE

2[ ] NO
9[ ] DK

e. Is this child alive today?

1[ ] YES: SKIP TO QUESTION 8 PAGE 8 358/
2[ ] NO: 1. When did the child die? ____ MONTH ____ DAY ____ YEAR 359/

2. What was the cause of death? 365/

____

____

3. In what city, county, and state did the death occur?

______________ CITY ______________ COUNTY ______________ STATE 366/

ASK ALL RESPONDENTS:

8. When did you first see a doctor for this pregnancy?______________ 367/
MONTH OF PREGNANCY

9. Were you using an IUD when you became pregnant?

1 [ ] YES 2 [ ] NO 9 [ ] DK 370/

10. Now, I'm going to ask you about some things that may have occurred during this pregnancy or in the three months before, that being from __________ of __________ 371/
MONTH YEAR

to __________ of __________.
MONTH YEAR

At anytime during this pregnancy or in the three months before did you have any of the following diseases or conditions:

	YES	NO	DK	IF YES: Was this before the pregnancy?	During what months of pregnancy?	
a. Diabetes?	1 [ ]	2 [ ]	9 [ ]	1 [ ]	__________	379/
IF YES: Did you take any medication for this?	1 [ ]	2 [ ]	9 [ ]	1 [ ]	__________	385/
__________ MEDICATION						
b. Hypertension or high blood pressure?	1 [ ]	2 [ ]	9 [ ]	1 [ ]	__________	391/
IF YES: Did you take medication to control it?	1 [ ]	2 [ ]	9 [ ]	1 [ ]	__________	397/
__________ MEDICATION						
c. Rubella or German measles?	1 [ ]	2 [ ]	9 [ ]	1 [ ]	__________	403/
d. Did you take any (other) prescription drugs anytime during this pregnancy or the three months before?	1 [ ]	2 [ ]	9 [ ]			409/

IF YES: What was it?

1) __________	1 [ ]	__________	410/
2) __________	1 [ ]	__________	
3) __________	1 [ ]	__________	

11. During this pregnancy or at the end of the pregnancy did you have any of the following complications:

	YES	NO	DK	IF YES: During what months of pregnancy?	
a. Pre-eclampsia, eclampsia, or toxemia?	1[ ]	2[ ]	9[ ]	______________	435/
b. Seizures?	1[ ]	2[ ]	9[ ]	______________	440/
c. Vaginal bleeding except at the end of the pregnancy?	1[ ]	2[ ]	9[ ]	______________	445/
d. Caesarean section? IF LB OR SB:	1[ ]	2[ ]	9[ ]		450/

IF YES: What was the reason for having a caesarean section? ______________________________ 451/

PROBE FOR MOST SPECIFIC INFORMATION KNOWN

12. At anytime during this pregnancy did you have a fever of 100° or more?

1[ ] YES: Did you have a fever: 452/

during the 1st 3 mos?	1[ ] YES	2[ ] NO	9[ ] DK	453/
" " 2nd 3 mos?	1[ ] YES	2[ ] NO	9[ ] DK	454/
" " 3rd 3 mos?	1[ ] YES	2[ ] NO	9[ ] DK	455/
at the end of the pregnancy?	1[ ] YES	2[ ] NO	9[ ] DK	456/

2[ ] NO
9[ ] DK

13a. About how much did you weigh at the beginning of this pregnancy? ________ LBS. 457/

b. How many pounds did you gain during this pregnancy? ________ LBS. 460/

14. In the three months before or at any time during this pregnancy, that would be from __________ of________, through _________ of _______, were you employed or did you do volunteer work? 463/

MONTH YEAR MONTH YEAR

1 [ ]YES 2 [ ]NO-SKIP TO QUESTION 15. 471/

	JOB #1	JOB #2	
a. What was your occupation or job?			472/
b. What industry was this job in?			476/
c. What was the name of the company or agency you worked for?			480/
d. In what city was that?			484/
e. What kind of activities did you do day to day at work?			488/
f. What month and year did you start this job?	____ ____ MONTH YEAR	____ ____ MONTH YEAR	508/
g. During what months of this pregnancy did you work at this job?			516/
h. How many hours/week did you work?			524/
i. Did you have any other jobs during this pregnancy?	1 [ ] YES - GO TO NEXT COLUMN, ASK 14a. 2 [ ] NO - GO TO QUESTION 14j.	1 [ ] YES - RETURN TO QUESTION 14a AND ATTACH SUPPLEMENT JOB FORM UNTIL ALL JOBS ARE COVERED. 2 [ ] NO - GO TO QUESTION 14j.	528/ 529/

14j. Did you have any type of work schedule other than only day-time hours during this pregnancy or in the 3 months before?

1 [ ] YES *2* [ ] NO: SKIP TO QUESTION 15 *530/*

IF YES: Did you work:

	Was this before pregnancy	During what months of pregnancy?	
a. Evenings only (3-11pm)?	*1* [ ]	____________	*531/*
b. Nights only (11pm - 7am)?	*1* [ ]	____________	*536/*
c. Rotate between 2 shifts?	*1* [ ]	____________	*541/*
d. Rotate between 3 shifts?	*1* [ ]	____________	*546/*
e. Other ____________ SPECIFY	*1* [ ]	____________	*551/*

15. Now I'd like to ask you about some exposures you may have had during this pregnancy or in the 3 months before.

a. Were you regularly, at least once a week, exposed to chemicals or solvents at home, at work, or in some other activity? For example, paint, laquer, varnish; organic chemicals or solvents such as paint thinner, gasoline, kerosene, fuel oil; or to pesticides or insect sprays.

1 [ ] YES *2* [ ] NO: SKIP TO QUESTION 15b *9* [ ] DK: SKIP TO QUESTION 15b *556/*

IF YES: What particular chemicals or solvents were you exposed to?

	CHEMICAL OR SOLVENT	Was this before the pregnancy?	During what months of the pregnancy were you exposed?	What were you doing?	How often?	
1)	____	____	____	____	____	*557/*
2)	____	____	____	____	____	*569/*
3)	____	____	____	____	____	*581/*
4)	____	____	____	____	____	*593/*

b. Were you regularly exposed to a video display terminal?

1 [ ] YES: ____ ____ ____ ____ *605/*
2 [ ] NO
9 [ ] DK *606/*

16. In the three months before this pregnancy or at any time during this pregnancy:

	YES	NO	DK	IF YES: Was this before the pregnancy?	During what month(s) of pregnancy?	
a. Did you have a chest x-ray?	*1* [ ]	*2* [ ]	*9* [ ]	*1* [ ]	________________	*615/*
b. Did you have a pelvic or abdominal x-ray?	*1* [ ]	*2* [ ]	*9* [ ]	*1* [ ]	________________	*621/*
c. Were you exposed to any other x-rays or other radioactive materials?	*1* [ ]	*2* [ ]	*9* [ ]	*1* [ ]	________________	*627/*
During this pregnancy:						
d. Did you have amniocentesis?	*1* [ ]	*2* [ ]	*9* [ ]		________________	*633/*
e. Did you have chorionic villus sampling?	*1* [ ]	*2* [ ]	*9* [ ]		________________	*638/*

17. Did you smoke cigarettes during this pregnancy?

1[ ] YES 2[ ] NO - SKIP TO QUESTION 18 9[ ] DK - SKIP TO QUESTION 18 643/

IF YES:

How much did you smoke:	1/2 pack a day or less	about pack a day	1-1/2 packs a day or more	not at all	
a. during the 1st 3 months	1[ ]	2[ ]	3[ ]	4[ ]	644/
b. during the 2nd 3 months	1[ ]	2[ ]	3[ ]	4[ ]	645/
c. during the last 3 months	1[ ]	2[ ]	3[ ]	4[ ]	646/

18. Did you drink any type of alcoholic beverages during this pregnancy -- any beer, wine, or hard liquor?

1[ ] YES 2[ ] NO - SKIP TO QUESTION 19 9[ ] DK - SKIP TO QUESTION 19 647/

IF YES:	about every day?	several times a week?	about once a week?	several times a month?	once a month or less?	not at all?	
a. During the 1st 3 months, about often did you drink:	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	648/
On days when you did drink about how many drinks did you have? 1[ ] 1 2[ ] 2-3 3[ ] 4+							649/
b. During the 2nd 3 months, about how often did you drink:	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	650/
On days when you did drink about how many drinks did you have? 1[ ] 1 2[ ] 2-3 3[ ] 4+							651/
c. During the last 3 months about how often did you drink:	1[ ]	2[ ]	3[ ]	4[ ]	5[ ]	6[ ]	652/
On days when you did drink about how many drinks did you have? 1[ ] 1 2[ ] 2-3 3[ ] 4+							653/

19. The next group of questions is about the liquids you drank during this pregnancy or for the three months before this pregnancy.

a. What types of liquids did you usually have each day during this time period?

b. About how many glasses, cups or ounces of liquids did you drink per day? Please include all sources of liquids; coffee, tea, soft drinks, juices, water, milk, beer, wine, other liquor, any liquid.

______________ or [ ] DK 654/
GLASSES OR CUPS
(8 ounces = approx. 1 cup)

c. During just the first trimester of this pregnancy was this amount different?

1[ ] YES: How many glasses or cups did you drink per day? ______________ 657/
GLASSES OR CUPS
2[ ] NO 658/
9[ ] DK

20a. At home, did you use bottled water at all during this pregnancy or for the three months before this pregnancy?
1[ ] YES 2[ ] NO: SKIP TO 21 9[ ] DK: SKIP TO 21 661/

b. Did you usually use bottled water at home? 1[ ] YES 2[ ] NO 9[ ] DK 662/

21. During this pregnancy or in the 3 months before did you use a water filter at your tap? 663/

1[ ] YES: 1. When did you begin using it? ______________ ____ 664/
MONTH YEAR

2. How often did you change it?
______________________________ 668/

2[ ] NO

9[ ] DK

22. Did you usually drink water from a private well during this time?

1 [ ] YES: Where was the well? ______________________ STREET ______________________ CITY 670/

2 [ ] NO 671/

9 [ ] DK

23a. At home, about how many glasses or cups of cold tap water or beverages made of unheated tap water did you drink each day? This should include any beverages made of unheated water such as orange juice, iced tea, or other beverages made from concentrate.

______________ GLASSES OR CUPS or [ ] NONE: SKIP TO 24
[ ] DK 672/
674/

b. And during just the first trimester of this pregnancy was this amount different?

1 [ ] YES: How many glasses or cups did you drink per day? ______________ GLASSES OR CUPS 675/

2 [ ] NO 676/
9 [ ] DK 678/

24. IF THE WOMAN DID NOT WORK DURING THIS PREGNANCY OR IN THE 3 MONTHS BEFORE SKIP TO QUESTION 26.

a. And at work, did you use bottled water at all during this pregnancy or for the three months before this pregnancy?

1 [ ] YES 679/

2 [ ] NO: SKIP TO 25

9 [ ] DK

b. Did you usually use bottled water at work?

1 [ ] YES 680/

2 [ ] NO

9 [ ] DK

25a. At work, about how many glasses or cups of cold tap water or beverages made of unheated tap water did you drink each day? This should include any beverages made of unheated water such as orange juice, iced tea, or other beverages made from concentrate.

[ ] NONE: SKIP TO 26 681/

__________ or [ ] DK: 683/

GLASSES OR CUPS

b. And during just the first trimester of this pregnancy was this amount different?

1 [ ] YES: How many glasses or cups did you drink per day? __________ 684/

AMOUNT

2 [ ] NO 685/

9 [ ] DK 687/

26. Were you nauseous during this pregnancy?

1 [ ] YES 2 [ ] NO -- GO TO QUESTION 27 688/

IF YES: How often were you nauseous:

	every day or almost every day	at least once a wk but not every day	less than once a week	not at all	DK	
a. During 1st 3 mo?	1 [ ]	2 [ ]	3 [ ]	4 [ ]	9 [ ]	689/
b. During 2nd 3 mo?	1 [ ]	2 [ ]	3 [ ]	4 [ ]	9 [ ]	690/
c. During Last 3 mo?	1 [ ]	2 [ ]	3 [ ]	4 [ ]	9 [ ]	691/

d. Did your nausea affect your consumption of cold drinks?

1 [ ] YES: Did your consumption increase or decrease? 1 [ ] INCREASE 692/

2 [ ] DECREASE 693/

2 [ ] NO, OR IT STAYED ABOUT THE SAME

9 [ ] DON'T KNOW

e. Did you take anti-nausea medication.

1 [ ] YES 2 [ ] NO 9 [ ] DK 694/

IF YES: What was that? __________

MEDICATION 695/

27. In the year before this pregnancy or any time during this pregnancy, was structural pest control or termite control work done in your residence?

1 [ ] YES 1. What chemical was used? ____________ or [ ] DK 697/
NAME 698/
2. What was the main pest being controlled? ____________ 699/

3. What was the name of the company that did the pest control work?

____________________ 700/

4. What month and year was the work done?

________ ________ 701/
MONTH YEAR

2 [ ] NO
9 [ ] DK

28. Now I'd like to ask a few questions about the father of this pregnancy.

[INTERVIEWER: CHECK PREGNANCY CALENDAR FOR THE APPROXIMATE MONTH AND YEAR CORRESPONDING TO 3 MONTHS BEFORE THIS PREGNANCY BEGAN.]

In just the 3 months before this pregnancy began, that would be from______of (MONTH) 19___ to _____ (MONTH) of 19___, was the father of this pregnancy employed or did he do volunteer work? 705/

1 [ ] YES 2 [ ] NO: SKIP TO QUESTION 29 9 [ ] DK: SKIP TO QUESTION 29 713/

In this job:	JOB #1	JOB #2	
a. What was his occupation?			714/
b. What was the name of the company or agency he worked for?			718/
c. In what city was that?			722/
d. What kind of activities did he do day to day at work?			726/
e. Did he have any other jobs during this time period?	1 [ ]YES: GO TO 28a AND SAY: In the other job he had: 2 [ ] NO: GO TO NEXT QUESTION	1 [ ] YES: GO TO 28a ATTACH FATHER'S SUPPLEMENTAL JOB FORM AND SAY: In the other job he had: 2 [ ] NO: GO TO NEXT QUESTION	736/ 737/

29. Which of the following best describes his race or ethnic group:

1[ ] Hispanic
2[ ] Black
3[ ] White
4[ ] American Indian
5[ ] Asian
6[ ] Or some other group? ________ 738/
SPECIFY
9[ ] DON'T KNOW

30. What's the highest grade in school that he had completed at the time of this pregnancy?

1 [ ] 0-8
2 [ ] 9-11
3 [ ] 12 (HIGH SCHOOL GRADUATE)
4 [ ] 13-15 (SOME COLLEGE OR TECHNICAL SCHOOL) 739/
5 [ ] 16 or more (COLLEGE GRADUATE)
9 [ ] DK

[ ] ADDITIONAL ELIGIBLE PREGNANCY: FILL OUT AND ATTACH THE "ADDITIONAL PREGNANCIES" FORM.

[ ] NO MORE ELIGIBLE PREGNANCIES: GO TO NEXT PAGE.

I'd like to conclude with a few more questions about yourself. 740/

31. How tall are you? __________ FEET __________ INCHES

32. Which of the following best describes your race or ethnic group:

1[ ] Hispanic 5[ ] Asian 743/

2[ ] Black 6[ ] Or some other group? __________ SPECIFY

3[ ] White 9[ ] DON'T KNOW

4[ ] American Indian

33. What is the highest grade in school that you have completed?

1[ ] 0-8

2[ ] 9-11

3[ ] 12 (HIGH SCHOOL GRADUATE) 744/

4[ ] 13-15 (SOME COLLEGE OR TECHNICAL SCHOOL)

5[ ] 16 or more (COLLEGE GRADUATE)

9[ ] DK

If we need to get in touch with you again, can you give me the name and address and telephone number of a relative, friend, or organization who would be apt to know how we can reach you if you move away?

____

____

Those are all my questions, do you have any questions you'd like to ask me before we finish the interview? ANSWER QUESTIONS OR REFER TO A SUPERVISOR.

Thank you very much for helping us in this study. We may want to review your medical records for more information about this (these) pregnancy(ies). If so, we will send you a consent form that asks you for permission to do so.

TIME INTERVIEW FINISHED __________

COMMENTS______________________________

____

____

NOTE IF RESPONDENT HAD DIFFICULTY WITH ANY QUESTIONS OR WAS UPSET OR DISTURBED BY THE INTERVIEW.

DHS/ESS/MW/6/3/86

Appendix B. Occupations Used In Classifying Solvent Exposure

Probably Solvent Exposed:

[a]48 Chemical engineers
73 Chemists, except biochemists
115 Chemistry teachers, postsecondary
188 Painters, sculptors, craft-artists
203 Clinical laboratory technologists
224 Chemical technicians
505 Auto mechanics except apprentices
506 Auto mechanic apprentices
507 Bus, truck, stationary engine mechanics
508 Aircraft engine mechanics
514 Auto body and related repairers
515 Aircraft mechanics except engine
518 Industrial machinery repairers
519 Machinery maintenance occupations
538 Office machine repairers
539 Mechanical controls and valve repairers
544 Millwrights
565 Tile setters, hard and soft
579 Painters, construction and maintenance
585 Plumbers, pipefitters, steamfitters
587 Plumber, pipefitter, steamfitter apprentices
637 Machinists except apprentices
639 Machinist apprentices
657 Cabinet makers and bench carpenters
658 Furniture and wood finishers
669 Shoe repairers
679 Bookbinders
703 Lathe and turning machine set-up operators
704 Lathe and turning machine operators
705 Milling and planing machine operators
734 Printing machine operators
735 Photoengravers and lithographers
748 Laundering and dry cleaning machine operators
753 Cementing and gluing machine operators
759 Painting and paint spraying machine operators
Hand painting, coating, and decorating

Possibly Solvent Exposed:

56 Industrial engineers
78 Biological and life scientists
83 Medical scientists
114 Biological science teachers, postsecondary
133 Medical science teachers, postsecondary
189 Photographers
213 Electrical and electronic technicians
223 Biological technicians

225 Science technicians, N.E.C.
523 Electronic repairers, communications and industrial equipment
525 Data processing equipment repairers
526 Household appliance and power tool repairers
533 Misc. electric and electronic equipment repairers
535 Camera, watch, musical instrument repairers
536 Locksmiths and safe repairers
547 Specified mechanics and repairers, N.E.C.
549 Not specified mechanics and repairers
634 Tool and die makers except apprentices
635 Tool and die maker apprentices
636 Precision assemblers, metal
645 Patternmakers and model makers, metal
649 Engravers, metal
654 Sheet metal worker apprentices
655 Miscellaneous precision metal workers
675 Hand molders and shapers except jewelers
678 Dental lab and medical appliance technicians
683 Elect and electronic equipment assembler
684 Miscellaneous precision workers, N.E.C.
695 Power plant operators
696 Stationary engineers
708 Drilling and boring machine operators
737 Misc. printing machine operators
745 Shoe machine operators
774 Photographic process machine operators
783 Welders and cutters
784 Solderers and brazers
785 Assemblers

[a]Number indicates 1980 U.S. Census Code.

Appendix C.

Is there more variation in spontaneous abortion rates than expected by chance?

Background

In the Pregnancy Outcome Follow-up Study a large number of spontaneous abortion rates have been estimated. There are four study areas and six study years each of which provides an independent estimate (Table 2.9). We ask: are these 24 estimates more variable than expected? To answer this question it is necessary to model the expected distribution. In this discussion we have assumed that each of these 24 estimates arises from an independent binomial experiment. We have assumed that the probability of "success" (in this case, pregnancy ending in spontaneous abortion) is constant over all 24 trials. We then fit a normal distribution to the observed rates.

Methods

A frequency distribution was constructed using the 24 observed rates. These range from .00 to .286 with a mean of .099. The observed and expected frequency distributions are contained in Table 2.C.1.

The numbers of pregnancies on which these rates are based range from 14 to 85. Rates in 1985 are based on only three months of data and sample sizes for this year are particularly small (14 to 21). Including 1985 data, the mean sample size was 43.25. To simplify matters it was decided to attempt to fit a normal distribution using a common sample size for all years and areas. It can be argued that if the data fit a normal distribution reasonably well under this assumption, the fit would be even better using the actual sample sizes.

Therefore, the expected frequency distribution was calculated assuming that the 24 data points are independent and identically distributed according to a binomial distribution with a success probability of 10% and a sample size of 43.

The observed and theoretical frequency distributions were then compared using the one-sample Kolmogorov-Smirnov statistic (1).

Results

The observed and theoretical distributions agree fairly well. The observed distribution is somewhat skewed, with a longer right tail. The maximum difference between the observed and theoretical frequency was 22.7% and occurred in the interval 0.04 to 0.06. The significance probability for this difference, using the one-sample Kolmogorov-Smirnov statistic, is about 0.15.

Discussion

Overall, the wide variation of spontaneous abortion rates seen in this study is not very different from what would be expected by chance, assuming that the rate for each year-census tract combination arose from a single repetition of a binomial trial in which the overall probability of success was 10%. The data from the original Fairchild study were unusual, in that these data included the lowest observed rate (0.0%) among the 24 estimates. This occurred in the control tract for that study in 1980. This study also found one of the highest rates (21.4%), which occurred in the exposed tract in 1981. The latter high rate is not suprising, since it was a cluster in that tract which brought about the study. This high rate was, in a sense, the "index case". However, the low rate in the control tract for 1980 can only be ascribed to chance, since, across all study years, rates in that tract averaged .096, which is very close to the overall mean.

Reference

1. Rohlf FJ, Sokal RR: Statistical Tables: Second Edition. WH Freeman and Co. San Francisco 1981, p. 204.

Table 2.C.1

Observed and Theoretical Cumulative Distributions

Value	Number of observations less than value	Cumulative Probability Observed	Theoretical	Difference
0.02	1	0.0417	0.0385	0.0033
0.04	3	0.1250	0.0922	0.0328
0.06	9	0.3750	0.1480	0.2270*
0.08	10	0.4167	0.3291	0.0871
0.10	13	0.5417	0.5000	0.0417
0.12	14	0.5833	0.6709	-0.0876
0.14	16	0.6667	0.8520	-0.1853
0.16	18	0.7500	0.9078	-0.1578
0.18	20	0.8333	0.9616	-0.1283
0.20	22	0.9167	0.9864	-0.0697
0.22	23	0.9583	0.9961	-0.0378
0.30	24	1.0000	1.0000	0.0000

* Maximum difference $\Delta = 0.2270$
Significance probability using one-sample Kolmogorov-Smirnoff statistic approximately 0.15.

Appendix D

Table 2.D.1

Number of Definite Spontaneous Abortions Among All Eligible Pregnancies[a]

	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(O)	5120.11(N)	BOTH	5120.08(O)	5053.0204(N)	BOTH	TOTAL
Exposed:							
1980	8	4	(12)	0	2	(2)	14
1981	14	6	(20)	10	8	(18)	38
1980-81	(22)	(10)	(32)	(10)	(10)	(20)	(52)
Unexposed:							
1982	12	7	(19)	9	6	(15)	34
1983	8	12	(20)	10	2	(12)	32
1984	17	11	(28)	17	3	(20)	48
1985	3	4	(7)	4	4	(8)	15
1982-85	(40)	(34)	(74)	(40)	(15)	(55)	(129)
TOTAL	62	44	(106)	50	25	(75)	181

O = Original study area
N = New study area

[a]Beginning before April, 1985

Table 2.D.2

Total Singleton Live Births Among All Eligible Pregnancies[a]

	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(O)	5120.11(N)	(BOTH)	5120.08(O)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	53	45	(98)	63	25	(88)	186
1981	44	60	(104)	64	28	(92)	196
(1980-81)	(97)	(105)	(202)	(127)	(53)	(180)	(382)
Unexposed:							
1982	59	65	(124)	42	45	(87)	211
1983	56	62	(118)	71	48	(119)	237
1984	62	97	(159)	70	57	(127)	286
1985	24	17	(41)	23	15	(38)	79
(1982-85)	(201)	(241)	(442)	(206)	(165)	(371)	(813)
TOTAL	298	346	(644)	333	218	(551)	1195

O = Original study area
N = New study area
[a] Beginning before April, 1985.

Table 2.D.3

Definite Spontaneous Abortion Rates Using All Pregnancies[a] by Year and Census Tract

	EXPOSED			UNEXPOSED			
TIME PERIOD	5120.12(O)	5120.11(N)	BOTH	5120.08(O)	5053.0204(N)	BOTH	TOTAL
Exposed:							
1980	13.1	8.2	(10.9)	0.0	7.4	(2.2)	7.0
1981	24.1	9.1	(16.1)	13.5	22.2	(16.4)	16.2
1980-81	(18.5)	(8.7)	(13.7)	(7.3)	(15.9)	(10.0)	(12.0)
Unexposed:							
1982	16.9	9.7	(13.3)	17.7	11.8	(14.7)	13.9
1983	12.5	16.2	(14.5)	12.4	4.0	(9.2)	11.9
1984	21.5	10.2	(15.0)	19.5	5.0	(13.6)	14.4
1985	11.1	19.1	(14.6)	14.8	21.1	(17.4)	16.0
1982-85	(16.6)	(12.4)	(14.3)	(16.3)	(8.3)	(12.9)	(13.7)
TOTAL	17.2	11.3	(14.1)	13.1	10.3	(12.0)	13.2

O - Original study area
N - New study area
[a] Beginning before April 1985

1594.tb5/11

Table 2.D.4

Odds Ratios And 95% Confidence Intervals For Spontaneous Abortions in Exposed and Unexposed Areas by Year Using All Eligible Pregnancies[a]

	ORIGINAL STUDY AREAS (5120.12/5120.08)		NEW STUDY AREAS (5120.11/5053.0204)	
	OR	95% CI	OR	95% CI
Time period				
1980	20.18[b]	(1.14, 357.77)	1.01[b]	(0.20, 5.10)
1981	2.04	(0.83, 5.00)	0.35	(0.11, 1.11)
(1980-81)	(2.88)	(0.30, 6.37)	(0.51)	(0.20, 1.29)
1982	0.95	(0.37, 2.46)	0.80	(0.26, 2.56)
1983	1.01	(0.38, 2.74)	3.88[b]	(0.95, 15.87)
1984	1.13	(0.53, 2.40)	1.94[b]	(0.56, 6.70)
1985	0.75[b]	(0.17, 3.37)	0.89[b]	(0.20, 3.87)
(1982-85)	(1.03)	(0.64, 1.66)	(1.55)	(0.82, 2.94)

[a] Beginning before April 1985

[b] Small sample adjustment

1594.tb6/11

Table 2.D.5

Stillbirths Among All Eligible Pregnancies[a]

TIME PERIOD	EXPOSED 5120.12(0)	5120.11(N)	(BOTH)	UNEXPOSED (5120.08(0)	5053.0204(N)	(BOTH)	TOTAL
Exposed:							
1980	1	1	(2)	1	0	(1)	3
1981	0	2	(2)	0	1	(1)	3
(1980-81)	(1)	(3)	(4)	(1)	(1)	(2)	(6)
Unexposed:							
1982	0	1	(1)	0	0	(0)	1
1983	0	0	(0)	0	0	(0)	0
1984	0	1	(1)	1	0	(1)	2
1985	0	0	(0)	1	0	(1)	1
(1982-85)	(0)	(2)	(2)	(2)	(0)	(2)	(4)
TOTAL	1	5	(6)	3	1	(4)	10

0 - Original study area
N - New study area
[a] Beginning before April 1985

1594.tbl/11

Appendix E. Multiple Logistic Models of Risk of Spontaneous Abortion

VARIABLE	Model 1	2	3	4	5	6	7
Any vs. no home cold tap water consumption	4.6	5.5	11.0	4.2	2.8	3.7	4.6
	(.0005)[a]	(.0005)	(.02)	(.009)	(.05)	(.03)	(.0005)
Mother's age:							
<20	2.7	2.6	4.3	1.8	2.8	2.6	2.6
20 - 34	1.0	1.0	1.0	1.0	1.0	1.0	1.0
35 +	2.9	2.2	1.8	2.8	1.6	1.7	2.6
	(.001)	(.008)	(.008)	(.08)	(.08)	(.17)	(.003)
Prior spontaneous fetal loss:							
0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
1	1.6	1.6	1.8	1.9	1.6	3.8	1.7
2+	2.1	2.4	3.0	2.2	1.4	4.8	1.4
	(.10)	(.09)	(.17)	(.20)	(.51)	(.0003)	(.24)
Ethnicity:							
White or Hispanic	1.0	NA	1.0	1.0	1.0	1.0	1.0
Other	0.3		0.4	0.1	0.1	0.3	0.3
	(.01)		(.20)	(.01)	(.05)	(.09)	(.02)
Alcohol consumption							
<4 drinks/wk	1.0	1.0	1.0	1.0	1.0	1.0	1.0
4 or more drinks/wk	1.5	1.4	2.3	0.9	1.3	0.6	1.7
	(.46)	(.55)	(.32)	(.88)	(.73)	(.60)	(.39)
Any vs no probable solvent exposure at work	4.8	3.2	6.7	2.2	5.7	.001	5.5
	(.008)	(.08)	(.03)	(.40)	(.01)	(0.86)	(.005)

	Model						
	1	2	3	4	5	6	7
Smoking:							
none	1.0	1.0	1.0	1.0	1.0	1.0	1.0
≤ 1/2 pack/day	1.1	1.1	0.4	1.9	0.8	0.9	1.1
1 or more packs/day	1.1	1.2	0.9	1.0	1.1	2.0	1.0
	(.96)	(.92)	(.49)	(.48)	(.93)	(.51)	(.94)
Any vs no water filter used beginning around time pregnancy began	0.4 (0.17)	0.3 (0.10)	0.6 (0.53)	0.2 (0.17)	0.0008 (0.71)	0.4 (0.31)	0.4 (0.18)
Time period and census tract:							
1980-81:							
original exposed (OE)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
new exposed (NE)	.17	.17	.36	.06	.23	.22	.12
original control (OC)	.20	.15	.14	.12	.20	.31	.25
new control (NC)	.90	.55	.78	.79	.56	.84	.83
1982-85:							
original exposed (OE)	.87	.92	.80	.79	.77	.57	.52
new exposed (NE)	.51	.50	.61	.34	.30	.25	.30
original control (OC)	.71	.72	1.08	.38	.91	.94	.41
new control (NC)	.38	.40	.54	.25	.29	.30	.22
	(.03)	(.09)	(.25)	(.10)	(.26)	(.13)	(.05)
(Rearrangement to compare exposed to unexposed areas)							
1980-81							
OE/OC	5.0	6.7	7.1	8.3	5.0	3.2	4.0
NE/NC	0.2	0.3	0.5	0.1	0.4	0.3	0.1
1982-85							
OE/OC	1.2	1.3	0.7	2.1	0.8	0.6	1.3
NE/NC	1.3	1.3	1.1	1.4	1.0	0.8	1.4

	Model						
	1	2	3	4	5	6	7
(N) SABs	92	88	39	52	44	40	87
(N) Live births	858	723	535	322	858	858	734
Goodness of fit p-valve							
Hosmer-Lemeshow	.63	.38	.73	.40	.94	.85	.60
C.C. Brown	.83	.95	.59	.46	.75	.92	.66

[a] p-valve

NA = not applicable

Model 1 Uses a single random eligible pregnancy per women; excludes women reporting IUD use at time of conception and women reporting using water from a private well.

2 Whites and Hispanics only.

3 Only women reporting nausea during first trimester.

4 Only women reporting no nausea during first trimester.

5 Only pathology confirmed SABs.

6 Only SABs of less than 10 weeks estimated gestational age.

7 Excludes pregnancies conceived in 1980.

3. Comparison of Original and Follow-up Fairchild Study Populations

Background

In 1983 interviewing was conducted for a study of pregnancy outcomes starting in 1980-1981 among women living in a residential area that had received drinking water contaminated with trichloroethane (TCA). The contamination resulted from a leak in an underground storage tank at a nearby industrial plant. The exposed study area consisted of one of the two census tracts considered most likely to have received the contaminated water based on their proximity to the well in which TCA was detected. A control census tract was selected based on demographic similarity to the exposed tract. The events leading to the discovery of the contamination, the concentrations of TCA found in the contaminated well, and the selection of the study areas has been covered in previous reports (1).

A comparison of pregnancy outcomes in the two areas showed that the exposed area had twice the rate of spontaneous abortion as the control area (21.5% compared to 11.0%). Subsequent analyses adjusting for potential maternal risk factors resulted in little change in the odds ratio determined from the unadjusted data.

In 1986, a household enumeration was carried out for a follow-up study to determine whether the spontaneous abortion rate difference between the two census tracts had changed following removal of the contaminated well from service, and whether the second presumptively exposed tract had experienced a similar excess. Current residents of both exposed tracts and two control tracts were interviewed concerning pregnancies that occurred during the period covered by the first study (1980-1981) as well as during the subsequent time period (1982-1985). This design offered the opportunity to make several interesting comparisons, as follows:

1. Comparison of interview responses and pregnancy outcomes in women who were interviewed in both studies, using data from both studies.

2. Comparison of interview responses and pregnancy outcomes in women who were in both studies with responses and outcomes of new residents, using data from the new study only.

3. Comparison of interview responses and pregnancy outcomes in women who were in both studies with responses of women in the first study who could not be located at the same address during the second study, using data from the first study only.

Methods

This report presents some results of the third comparison, reanalysis of the first Fairchild study results separately for women who had changed their place of residence and those who had remained at the same address. For ease of comparison with the original Fairchild results on the entire group, the same variables were used, and the population at risk was defined in the same way as in Fairchild I. Thus, eligible women had lived within their respective study areas for the entire pregnancy, the pregnancy began between January 1, 1980 and December 31, 1981, and ectopic pregnancies and pregnancies resulting in twins were excluded. Spontaneous abortions reported by the mother but not medically confirmed were included. Of the 401 Fairchild I pregnancies, 236 pregnancies occurred among women who had remained at the same street address and 165 among women who had moved away or could not be reached for other reasons (refusals, unable to locate) and thus were not included in Fairchild II.

Results

Results of analysis show that the crude odds ratios comparing the spontaneous abortion rates in the two census tracts differ in the two groups of women, 2.79 (95% confidence interval 1.99, 3.59) for women who resided at the same address three years later, 1.74 (95% confidence interval 0.97, 2.51) for women not located at the same address three years later, (Table 3.1). However, the 95% confidence intervals overlapped, as shown above, indicating that the difference between the odds ratios was not significant at the 5% level. The spontaneous abortion rates were lower among women who had remained in both the exposed and the control areas (19.3 and 7.9 respectively) than among women who had left

(24.4 and 15.7 respectively). The results were similar when the pregnancies at risk were redefined to exclude stillbirths, therapeutic abortions, and unconfirmed spontaneous abortions.

The odds ratios and regression coefficients of the multiple logistic regression analysis are given in Table 3.2 along with the 95% confidence intervals for census tract. The distributions of each of the variables in the control and exposed census tracts are shown in Table 3.3. The main features of these tables are as follows: The adjusted odds ratio comparing census tracts was greater than 2.00 regardless of whether the women could be located at the same address three years later; however, it was somewhat lower and not statistically significant among the women who had apparently moved from the area. The significant effect of tap water and alcohol consumption on the spontaneous abortion rate that was found in the original study occurred principally among the women who later moved, and adjustment for these factors might be at least partially responsible for the lower adjusted odds ratio for census tract in this group of women.

The finding of greatest interest was that in both census tracts the rate of spontaneous abortion was considerably lower among women located at the same address after three years compared to those women who had apparently moved away.

Reference

1. Epidemiological Studies Section, California Department of Health Services: Pregnancy Outcomes in Santa Clara County 1980-1982: Reports of Two Epidemiological Studies. California State Publications Section. Report 7540-958-1301-5.

Table 3.1

Total Reported Spontaneous Abortions
by Population at Risk and Census Tract

	CONTROL			EXPOSED			
	N (Pregnancies)	N (SAB)	%	N (Pregnancies)	N (SAB)	%	Odd Ratios
Fairchild I Total	210	23	11.0	191	41	21.5	2.22
Same residence three years later	127	10	7.9	109	21	19.3	2.79
Not located three years later	83	13	15.7	82	20	24.4	1.74
Fairchild I Total	203	21	10.3	180	35	19.4	2.09
Same residence three years later[a]	125	10	8.0	106	19	17.9	2.51
Not located three years later[a]	78	11	14.1	74	16	21.6	1.68

[a]Excluding therapeutic abortions, unconfirmed spontaneous abortions, and stillbirths.

Table 3.2

Multiple Logistic Regression Results
Comparing Women Who Stayed With Women Who Left

	TOTAL	Same address 3 yrs later	Not located 3 yrs later
Number of pregnancies	401	236	165
Number with missing data	8	5	3
Number in analysis	393	231	162
Number of spontaneous abortions	64	31	33
Rate per 100 pregnancies	16.0	13.1	20.0
Census tract			
OR (exposed vs control)	2.35[a]	2.49[a]	2.05
95% confidence limits			
Lower	1.30	1.08	0.83
Upper	4.23	5.72	5.04
Risk factor		Coefficients	
Cold tap water[b]	2.13[a]	1.20	4.10[a]
Previous pregnancies[b]	0.88	0.83	1.02
Previous spontaneous abortions and stillbirths[b]	1.37	1.71	0.78
Age of mother < 20	1.58	0.00	1.36
Age of mother > 34	1.89	0.64	4.47
Smoking (first trimester)[b]	0.97	0.36	1.20
Alcohol (first trimester)[b]	1.48[a]	1.37	1.80[a]
Non-White	0.70	0.55	0.75
Occupational exposure (first trimester)	1.03	1.66	0.44
Month pregnancy identified[b]	0.69	0.67	0.75

[a] Significant at the 5% level.

[b] Logistic coefficients representing the increase in relative risk for moving from one category of the variable to the next highest. Odds ratios for other variables.

Notes: Cold tap water categories are the same as on Table 3.3. Previous pregnancies, previous spontaneous abortions and stillbirths, and month pregnancy identified are actual counts. Smoking and alcohol are as originally coded on the questionnaire. Occupational exposure is exposure to at least one of the following substances at least once a week during the first trimester of pregnancy: paint, lacquer or varnish; organic chemicals or solvents; gasoline, kerosene, fuel oil or other petroleum products; pesticides or herbicides; x-rays or radioactive material.

Table 3.3

Percent Distribution of Population Subgroups by Maternal Risk Factors

	Same address 3 yrs later		Not located 3 yrs later	
	Control	Exposed	Control	Exposed
Total number of pregnancies	127	109	83	82
Home tap water consumption				
None	14.2	10.3	9.8	15.0
1-3 glasses/day	41.7	39.3	39.0	23.8
4 or more glasses/day	44.1	50.5	51.2	61.3
Number of previous pregnancies				
0	20.5	20.2	28.9	30.5
1	33.9	35.8	34.9	31.7
2	25.2	18.4	14.5	23.2
3+	20.5	25.7	21.7	14.6
Number of previous spontaneous abortions or stillbirths				
0	73.0	73.4	72.3	74.4
1	19.0	16.5	18.1	20.7
2+	7.9	10.1	9.6	4.9
Age of mother				
Less than 20	0.0	0.9	8.4	7.3
20-34	90.6	96.3	83.1	86.6
35 or greater	9.5	2.8	8.4	6.1
Amount of smoking				
None	85.0	93.6	78.3	84.2
1/2 pack/day or less	8.7	3.7	13.3	8.5
One pack/day or more	6.3	2.8	8.4	7.3
Alcohol consumption				
Never	69.0	69.7	69.9	72.0
Once a month or less	21.4	16.5	18.1	17.1
Several times/month	4.8	1.8	4.8	4.9
About once/week or more	4.8	11.9	7.2	6.1
Ethnicity				
Non-White	18.1	18.4	19.3	26.8
White	81.9	81.7	80.7	73.2

Table 3.3 (Continued)

	Same address 3 yrs Later		Not located 3 yrs Later	
	Control	Exposed	Control	Exposed
Month decided pregnant				
First	31.5	33.3	41.0	28.4
Second	55.9	60.2	53.0	58.0
Third or later	12.6	6.5	6.0	13.6
Occupational exposure (first trimester)	3.9	3.7	6.0	3.7

Note: Percents are based on totals minus missing values.

4. Cardiac Study: Follow-up Cluster Investigation

BACKGROUND

On November 17, 1981, it was discovered that a leak of toxic chemicals had occurred from a storage tank located about 2,000 feet from a well (Well #13) which supplied drinking water to nearby residences and industries. When Well #13 was removed from service on December 7, 1981, 1,1,1-trichloroethane (TCA) was found in this well at 1700 parts per billion (ppb). An epidemiologic investigation was conducted by the California Department of Health Services (CDHS) which found a 2.2-fold excess prevalence of severe cardiac anomalies in the area potentially served by the contaminated water supply for births occurring in the period January 1981 through August 1982 compared with births in the remainder of SCC (1,2). That study was not able to identify any sources of bias which could explain the excess prevalence seen.

However, the relation between the leak and the prevalence of cardiac anomalies remained uncertain due to the temporal and geographic pattern of the cases relative to the leak (1,2). No excess was found for the succeeding time period, September 1982 through December 1983 (2). On the basis of these findings, the CDHS concluded that a follow-up study be conducted of this excess prevalence. This study was limited in time to the period, January 1, 1981 through September 6, 1982, and in space to children

born in the seven census tract area served by the water system in which contamination had been found.

The objectives of the follow-up study reported here were: (i) to determine whether potential confounding factors other than those examined in the earlier investigation (1,2) explained some the excess of cardiac anomalies; and (ii) to determine whether the effect estimate for cardiac anomalies among children, based on a crude measure of exposure, increased or decreased when exposure to the contaminated water supply was more accurately classified. In the earlier study, exposure was defined by place of birth; exposed cases were those whose residence at time of birth was within the seven census tract area potentially served by the contaminated water supply, hereafter referred to as the study area. If exposure to the water supply had increased the risk, using more accurate exposure information should result in an increased estimate of relative risk. In contrast, if the effect estimate was significantly decreased after correcting for misclassification, it suggests that the original measure of exposure was not indicative of exposure to the water supply or that exposure was not related to risk.

There are four ways misclassification with respect to exposure could have occurred: (i) cases called exposed were not actually exposed, e.g., mother did not live or spend time in the study area during the critical time period for cardiac development or mother did live in the study area but did not drink tap water; (ii) cases called unexposed were actually exposed, e.g., mother lived in the study area during the critical period of gestation but moved before giving birth or mother exposed regularly to the contaminated

water supply but lived outside the study area; (iii) non-cases called exposed were not actually exposed (same reasons as [i] above); and (iv) non-cases called unexposed were actually exposed (same reasons as [ii] above). Another potential source of misclassification is the possibility that homes of case and control mothers within the study area did not receive TCA contaminated water from Well #13 during the relevant time period of gestation.

This report compares maternal exposures from the study area water supply with maternal water exposures from the remainder of SCC for children born in the period January 1, 1981 through September 6, 1982 with and without severe cardiac anomalies.

METHODS

The study period corresponded to births occurring between January 1, 1981 through September 6, 1982. This time period was determined based on the critical period during gestation for cardiac development and the date of closure of Well #13. Cardiac development occurs from approximately the third to the seventh week post-conception. In the absence of knowledge of the metabolic characteristics of a particular exposure it is reasonable to assume that any exposure from conception through the seventh week of gestation is relevant. The well was closed on December 7, 1981, and it was assumed that exposure to the contaminated water would still be possible for a subsequent week, i.e., through December 14, 1981, to allow thorough transport of water through the system. If a woman consumed water and also

conceived on December 14, 1981, her baby would be the last birth at risk for exposure. Her expected delivery date would be September 6, 1982 based on a 38 week gestation. Thus, September 6, 1982 represents the last date a child would be born that would have had potential in-utero exposure to the contaminated water supply.

The follow-up study was case-control in design. Children with severe congenital cardiac disease (cases) diagnosed within the first year of life were ascertained by the California Birth Defects Monitoring Program among live births in SCC for the study period. A cardiac anomaly included a diagnosis of cardiac malformation (745-747.9, International Classification of Diseases-9) made by echocardiogram, catheterization, surgery, or autopsy. Excluded as cases were; septal defects, patent foramen ovale, patent ductus arteriosus in a premature infant (less than 38 weeks), pulmonic stenosis, arrhythmia, or functional murmur, unless accompanied by congestive heart failure or any other cardiac anomaly. Septal defects were included if their diagnosis was made by invasive diagnostic procedures (surgery or catheterization).

In the earlier study performed by the CDHS, all live births in the study area (N=2151) and in the remainder of SCC (N=36,592) were included to obtain prevalence measures of cardiac anomalies in presumptively exposed and unexposed areas. The ratio of these two measures yielded a 2.2 (95% CI=1.2, 3.9) fold excess of severe cardiac anomalies in the study area compared to the rest of SCC. For the follow-up study, a representative sample of all live births in the county was selected to serve as controls. The number of control births was approximately equal to the number of cases and was

obtained through random selection of vital records for all live births in SCC for the same time period as the cases.

The study identified 106 children born in the study period with severe cardiac anomalies. Mothers were found and interviewed for 83 (78.3%) cases. Of the 114 controls identified from the vital records files, 96 (84.2%) mothers were found and interviewed. The primary reason that either a case mother or a control mother was not interviewed was the inability to locate her after extensive tracing efforts. A new control mother was not substituted by resampling the vital statistics files when a control mother was not located. Resampling was not conducted because it was thought that such a strategy would bias the control group towards mothers who were more likely to have remained at one address.

Interviews were conducted over the telephone or in-person when necessary. In an effort to obtain information on all maternal water exposures, the mother of each case or control was queried on her residence address(es), location of her place of employment, and places she frequently visited during the first trimester of her pregnancy with the index child. She was asked about her consumption of both tap and bottled water for the same time period. She was also asked about the frequency and duration of showering and bathing both at home and at places she frequently visited. In addition, each mother was asked about numerous other potential risk factors for congenital cardiac anomalies such as alcohol consumption, education, employment, age, nausea, race, cigarette smoking, diabetes, epilepsy, and family history of cardiac disease.

This report presents effect estimates for cardiac anomalies and first trimester maternal exposures to water (drinking, bathing, or showering) in the study area relative to the rest of SCC. Analyses of maternal water exposures to the study area and to the rest of SCC were also performed with adjustment for a number of potential confounders. The measure of association used was the odds ratio (OR). Confidence intervals (95 per cent) were calculated using Epistat software (3). When an observed value of an individual cell was less than five, the small sample size adjustment procedure according to Gart (4) was used. The summary procedure according to Woolf (5) was used to adjust for potential confounders.

Also presented in this chapter is a comparison of cases and controls within the study area with respect to estimated TCA exposure via water. TCA exposure for cases and controls in the study area was estimated using hydrogeologic modelling methods (6). These data were obtained for 1981 from the Great Oaks Water Distribution Study conducted as part of the CDHS effort to follow-up on the industrial leak of 1981. A detailed discussion of that study can be found elsewhere (6). Briefly, the water distribution study provided estimates of the probability of receiving water from Well #13 for each month in 1981 by small areas within the water distribution system and the estimated concentration of TCA in water from Well #13 each month.

With this information, a cumulative maternal TCA exposure score for the first trimester was obtained for cases and controls whose birth address was located within the study area. The seven census tracts in the study area were ranked on the estimated exposure to Well #13 for each month. A census tract was ranked 1 if it received the largest proportion of Well #13 water

first trimester. For the control mothers, all six mothers who had a child born within the study area also lived in the area during the first trimester. In addition, one control mother who had a child born outside the study area had lived in the study area during the first trimester. Thus, the change in OR from 2.0 for cardiac anomalies and birth address in the study area to 1.4 may be explained by one case based on birth address being removed from the study area (misclassification of 11.1%) and one control mother being added to the study area (misclassification of 16.6%).

Maternal water exposures were examined to correct for possible misclassification of exposure among women who drank no tap water. Comparing mothers who lived in the study area during their first trimester and who drank at least one glass of tap water per day to mothers who lived outside the study area for their first trimester and drank at least one glass of tap water per day revealed an OR of 2.3 (0.61, 8.4). Thus, correcting this source of misclassification increased the OR from 1.4 to 2.3. These data are shown in Table 4.3.

The association between residence inside the study area and consumption of tap water was also examined in the presence of a number of potential confounders, namely maternal alcohol consumption, education, employment, age, nausea, race, cigarette smoking, diabetes, epilepsy, and family history of cardiac anomalies. The adjusted ORs were all generally lower than the unadjusted OR of 2.3 and are shown in Table 4.4. This was particularly true when the OR was adjusted for maternal education level (OR_{Woolf}=1.5, 95% CI= 0.44, 5.4).

A somewhat elevated OR (OR=2.0 95% CI= 0.58, 6.7) was also found for cardiac anomalies and maternal residence in the study area and showering or bathing more than 50 minutes per week compared to maternal residence outside the study area and showering or bathing for the same length of time (Table 4.3).

Among the 18 case and control mothers who reportedly frequented (defined as time spent within SCC at least twice a week or for one week or more) areas within SCC other than at home or work during the first trimester, four case mothers (none of whom resided in the study area) and one control mother reported visiting the study area, and seven case mothers and six control mothers reported visiting a location outside the study area (Table 4.3). The OR for cardiac anomalies and frequent visits to the study area was 2.6 (0.31, 21.8). The OR for cardiac anomalies and maternal frequent visits to the study area and water consumption (any tap water versus none) was 1.4 (0.15, 13.2).

Case and control mothers were also asked whether they regularly showered or bathed at a place in SCC other than at home. No case or control mothers reported showering or bathing regularly in the study area. Similarly, no case or control mother reported their work location during the first trimester to be in the study area.

Water Distribution Study Data

As outlined above, the first trimester exposure to TCA in drinking water was estimated by ranking cases and controls based on their census tract of

birth. This analysis was not limited to the cases and controls whose mothers were interviewed, but rather included all cases and controls identified for the study. Therefore, for this analysis there were 12 cases and 7 controls born in the study area. In addition, 19 births were randomly selected from the SCC vital statistics file of live births to also serve as controls. This provided 12 cases and 26 controls for which to obtain estimated first trimester TCA scores. If the first trimester of a case or a control was in 1980, we were unable to assign a score due to the fact that TCA data were unavailable for 1980 from the Great Oaks Water Distribution Study (6). However, based on the hydrogeologic modelling it is unlikely that there was any TCA exposure in 1980 (6).

Of the 12 cases born in the study area, we were able to assign a score to five. Of the 26 controls, we were able to assign a score to 25. It should be noted that the 19 additional controls were chosen so that their first trimester would have been in 1981 so that a score could be assigned. The mean TCA score for cases was 416.4 and for controls was 586.4. The lower score seen for the cases is an indication that cases were somewhat more likely to have been exposed to TCA. These data are displayed in Table 4.5.

Because we observed a mean difference in scores based on birth address, we also looked at TCA scores exclusively for those cases and controls for which interview data were available on residence during first trimester and consumption of tap water in the study area. However, this analysis was limited to only six cases and four controls. For the case mothers, two lived in the study area and drank tap water and four frequently visited the study area and drank tap water. For the control mothers, three lived in the

study area and drank tap water and one fr quently visited the study area and drank tap water. The mean TCA scores for cases and controls for this analysis were, 271.4 and 473.3, respectively. These data are shown in Table 4.6. Again, the lower average score for cases compared with controls suggests more TCA exposure for case mothers during the first trimester.

DISCUSSION

In an earlier report (2), it was concluded that the temporal distribution of cardiac cases was some evidence that the leak into Well #13 identified in 1981 was unlikely to have accounted for the entire excess observed in the study area. While the time of onset of the leak in Well #13 is uncertain, solvent levels must have increased between the time of initial leak and its discovery in December 1981 over a period of many months. If this contamination was responsible for the observed excess of cardiac anomalies, one might expect to see the number of cases among full-term births increasing throughout 1981 and into the summer of 1982, i.e., toward the end of the study period. However, the 10 case children born in the study area in 1981 occurred at a frequency of approximately one per month. In addition no children with severe cardiac anomalies (all of whom were full-term births) were born in the study area between May and December 1982 (2).
If the leak was the explanation, we would have expected to observe a similar frequency of children with cardiac anomalies in the first nine months (until 9/6/82) of 1982 as was seen in 1981. Since nine cases, who had first trimester exposure to the study area, occurred in the 12 months of 1981, one would have expected to observe approximately seven cases in the first nine

months of 1982. However, only two cases (both in April) occurred in the study area at this time. The absence of cases between January 1, 1982 and September 6, 1982 was statistically significant (p=0.03).

Thus, even though the prevalence of cardiac anomalies was higher among 1981 births in the study area than the rest of SCC and was not higher for 1982 and 1983 births (a pattern which might be argued as consistent with the leak), the drop in the prevalence of cardiac anomalies in the study area began four months before one would have expected to observe a decreased prevalence based on the time of closure of Well #13.

The present study suggests that the findings from the earlier CDHS study of a 2.2 fold excess prevalence were not due to confounding bias or severe errors in classification of exposure to the contaminated water supply. Slightly elevated ORs were identified in this study for cardiac anomalies and maternal residence in an area of SCC which potentially received contaminated drinking water in 1980 and 1981. These ORs were found for case mothers who lived or frequently visited the area and drank tap water and for case mothers who lived in the area and showered or bathed more than 50 minutes per week.

However, all of the elevated ORs identified had associated confidence intervals which included 1.0, which suggests that sampling variability is a possible explanation of these results. It is important to emphasize that because these results are based on small numbers, any error in reporting or recording exposure status could severely influence the effect

estimates found. This is particularly true for those cases and controls whose residence was in the study area.

Further, the effect estimates could also be influenced if the mothers of case and control children not located for interview were different from those mothers that were interviewed with respect to residence in the study area or tap water consumption. There were three case mothers and one control mother who had a child born in the study area and were not interviewed in this study. If the three case mothers were tap water drinkers and lived in the study area during the first trimester, and the one control mother was not a tap water drinker, then the OR would be 3.2 rather than the OR calculated of 2.3. In contrast, if the one control mother was a drinker and the case mothers were not then the OR would be 1.8.

Based on the estimated TCA concentration in the study area water, this study found some evidence to suggest that case mothers were somewhat more likely to have had TCA exposure from their drinking water than control mothers at a time period in gestation critical for cardiac development. The limitations of this estimation process have been described elsewhere (6).

<u>References</u>

1. Epidemiological Studies Section, California Department of Health Services. Pregnancy outcomes in Santa Clara County, 1980-1982: Reports of two epidemiological studies. California State Publications Section. Report 7540-958-1301-5, 1985.

2. Swan SH, Shaw GM, Harris J, et al: Congenital cardiac anomalies in relation to water contamination: Santa Clara County, California. 1981-83. Submitted for publication 1988.

3. Gustafson TL: Epistat statistical package for the IBM personal computer, version 3.0. 1984.

4. Fleiss JL: Statistical methods for rates and proportions. Second Edition. New York. 1981.

5. Woolf B: On estimating the relation between blood group and disease. Ann Hun Genet 1955; 19:251-3.

6. Murphy P: The Great Oaks water distribution study. 1988.

Table 4.1

Cases and Controls Born Inside and Outside the Study Area

Place of Birth Relative to Study Area	Cases	Controls	OR	95% CI
Inside	12	7	2.0	(0.47, 5.2)
Outside	94	107	---[a]	

[a]Referent group.

Table 4.2

Cases and Controls By Maternal Residence During First Trimester Relative to Study Area

Residence During First Trimester Relative to Study Area	Cases	Controls	OR	95% CI
Inside	8	7	1.4	(0.47, 3.9)
Outside	75	89	1.0[a]	

[a]Referent group.

Table 4.3

Maternal First Trimester Residence, Employment, or Frequent Visits to the Study Area Compared to SCC

	Residence					
	Inside Study Area		Outside Study Area			
Maternal Exposure	Cases	Controls	Cases	Controls	OR	95% CI
Resided & drank tap water	7	3	72	76	2.3	(0.61, 8.4)
Resided & showered/ bathed >50 minutes per week	7	4	60	71	2.0	(0.58, 6.7)
Frequently[a] visited	4	1	7	6	2.6	(0.31, 21.8)
Frequently visited & drank tap water	4	1	7	3	1.4	(0.15, 13.2)

[a]Mothers who frequently visited the study area were not the same mothers who resided and drank tap water in the study area.

Table 4.4

Odds Ratios for Cardiac Anomalies by Home Tap Water Consumption Inside Versus Outside Study Area After Adjustment for Potential Confounders

Variable	OR[a] Woolf	95% CI	Homogeneity Chi square	df	p
Alcohol	2.2	(0.63, 7.5)	0.25	2	0.88
Education	1.5	(0.44, 5.4)	2.4	3	0.49
Employment	2.3	(0.64, 8.3)	0.03	1	0.87
Maternal Age	1.9	(0.29, 12.4)	3.5	2	0.17
Nausea	2.1	(0.58, 7.4)	0.37	1	0.54
Race	1.7	(0.44, 6.3)	2.7	2	0.26
Smoking	2.0	(0.57, 7.2)	2.0	2	0.37
Family history	2.2	(0.62, 7.6)	0.03	1	0.95
Income	2.0	(0.60, 6.5)	0.12	2	0.94
Maternal diabetes	1.7	(0.48, 6.3)	0.02	1	0.90
Maternal epilepsy	2.0	(0.55, 6.9)	1.2	1	0.28
Sex of child	2.0	(0.54, 7.3)	1.1	1	0.29

Unadjusted OR 2.3 (0.61, 8.4)

[a]Any tap water consumed inside study area at home residence versus any tap water consumed outside study area at home residence during the first trimester.

Table 4.5

Estimated TCA Score For Cases and Controls Born In the Study Area

	Cases	Controls
No.	12	26[a]
No. with scores assigned	5	25
Sum of score	2081.8	14661.2
Range	4.0 - 990.0	4.0 - 1385.0
Mean score	416.4	586.4

[a] 19 additional live births were selected from vital statistics files to give an approximate 1:5 ratio of cases to controls.

Table 4.6

Estimated TCA Score for Cases and Controls Where Maternal Drinking Water Exposure[a] Was Obtained By Interview

	Cases	Controls
No.	11	5
No. with scores assigned	6	4
Sum of score	1628.5	1893.0
Range	4.0 - 990.0	37.0 - 990.0
Mean score	271.4	473.3

[a]Mother resided or frequently visited the study area and drank tap water during her first trimester.

5. Material Mass Balance Analysis

Introduction

The California Department of Health Services (DHS), in collaboration with its contractor, the California Public Health Foundation, has been conducting several epidemiological and environmental studies in Santa Clara County, California. The epidemiological studies were undertaken as follow-up studies to previous investigations of the possible reproductive health effects of drinking water potentially contaminated by several organic chemicals, including low levels (≤ 11 ppb) of freon, 1,1 dichloroethylene (DCE), and high levels (in the range of 2000 ppb) of 1,1,1 trichloroethane (TCA). For TCA, the California State Action Level and the proposed Maximum Contaminant Level (MCL) for drinking water standards is 200 ppb. The environmental studies have been performed primarily to provide exposure data for the epidemiological studies. For the latter studies, investigators need to know, as accurately as possible, who was exposed, to what chemicals, and when the exposure began. This report presents the findings of one of those environmental studies.

Background

In late November 1981, Fairchild Semiconductor Corporation (formerly Fairchild Camera and Instrument Corporation) discovered that one of its two underground tanks storing solvent wastes at their South San Jose facility had failed, allowing the stored waste to leak into the surrounding soil. The mixture of wastes stored in the tank were regulated according to California and federal hazardous waste management laws. Fairchild notified appropriate local and state regulatory agencies and the Great Oaks Water Company (GOWC) about the leak. GOWC was the owner and operator of a municipal water supply well (GOWC #13) which was approximately 2000 feet downgradient from the failed tank. The GOWC distribution system serves groundwater to seven census tracts in Santa Clara County. Fairchild also requested of GOWC to conduct water quality tests on well #13. GOWC agreed and shut off well #13 from the rest of the water distribution system. Well #13 was never returned to service within the system.

Fairchild did not know the extent of the environmental contamination resulting from the leak because the time that the leak began and the exact mixture and amount of chemicals which had leaked from the tank were unknown. However, TCA, acetone, xylene, isopropyl alcohol (IPA), freon and other proprietary mixtures of solvents were used by the company. Fairchild did not know exactly which of these chemicals leaked from the failed solvent waste tank because only a portion of the solvent wastestream was collected in the tank, while other solvent wastes were collected in drums. The initial water quality testing performed by Fairchild found 1700 to 1800 ppb of TCA in well #13. A few days later samples were taken for water quality testing on all GOWC wells. No other wells showed contamination except well #8 which had 17 ppb of TCA. The contamination of well #8 was considered to be related to chemical releases from a nearby IBM facility. The concentration of TCA at well #13 had increased to 5700 ppb. Continuous testing over the next four months of well water showed TCA concentrations ranging from 2800 to 8800 ppb in Well #13 and from 0.1 to 27 ppb in well #8. Well #8 was removed from GOWC service in March 1982. Freon was detected in well #8 at 25 ppb in April of 1982. Freon and DCE (a degradation byproduct of TCA and a contaminant in the manufacture of TCA) were detected in well #13 from April to July 1982 in the range of 3-11 ppb for each.

Residents of the neighborhoods in the vicinity of the contaminated well #13 became very concerned over the possible health effects of drinking water contaminated with these industrial chemicals. Some residents were particulary concerned about spontaneous abortions and cardiac defects in nearby homes. In response to these concerns, DHS conducted two epidemiological studies of pregnancy outcomes and cardiac defects in the area to address the problem. The results of these studies were reported in January 1985[1]. The authors used 1980 as the beginning of potential exposure because of the uncertainty of the date of onset of the chemical release.

Following the discovery of contamination, the California Bay Area Regional Water Quality Control Board requested Fairchild to determine the extent of the chemical leakage from the failed tank. Fairchild conducted a study and prepared a report of their findings entitled "Fairchild South San Jose

Material Balance Report May 11, 1982."[2] A copy of the report is included as Appendix A of this report. The introductory paragraph of the report states, "This material balance report for solvent materials at Fairchild's South San Jose facility was prepared at the request of the Regional Water Quality Control Board. Fairchild has fully cooperated with the Board and other interested public agencies, and has attempted to determine as precisely as possible the extent of the discharge of solvent materials into the ground at the South San Jose facility following the failure of a solvent waste storage tank."[3] The introduction to the report further states, "The results of this study are based on an exhaustive review of current data, and support the view that solvent balance measurements are, at best, imperfect and that a variance of up to ten percent (10%) is to be expected."[4] The study report concludes that, "the maximum number of gallons of solvent which may have been lost appears to be 58,394 and "The data, therefore, tends to indicate that the solvent waste tank failed, at the earliest, after mid-1980."[5]

DHS regarded the Fairchild Material Balance Report (MBR) as a potential source of information regarding environmental exposure data needed for the interpretation of their epidemiological studies. However, it was necessary to analyze this report with respect to completeness and accuracy before it could be relied upon. The goal of the present analysis is to qualitatively assess the accuracy of the report's conclusions regarding the date the leak began. It is not intended to be a complete audit of the Fairchild report or a precise estimate of all the chemicals lost. Given these limited goals, DHS allocated $10,000 and nine months to complete the review.

The date the leak began is particularly important for interpreting the results of the follow-up epidemiological studies of pregnancy outcomes. It helps to define the period in which residents were potentially exposed to chemicals found in the drinking water. Determining the amount of chemicals spilled is also of interest because it is an important factor in Fairchild's assessment of when the leak began.

Determining what chemicals were spilled is important because the epidemiological studies are concerned with the reproductive effects of the exposure. Prior to conducting the first epidemiological study, a review of animal data was performed. No study found TCA to be teratogenic in laboratory animals. The toxicological data for DCE was similar. The researchers reviewed the toxicological data for freon, xylene, and IPA as well, and concluded that these chemicals were not causes for concern. However, glycol ethers, which are widely used in the semiconductor industry (including Fairchild), are of concern since they are known reproductive toxins. Unfortunately, no tests to determine the presence of glycol ethers in well water were conducted at the time the other chemical contamination was identified. The reproductive effects of mixtures or other unmeasured chemicals are, similarly, unknown.

METHODS

Material Balance Analysis

A material balance analysis is commonly used in engineering studies to assess the inflow and outflow of substances through systems. Solvents are the substances of concern in the Fairchild analysis because the waste storage tank that failed was specifically intended for solvent waste. Therefore, the balance equation in the case of the Fairchild spill is: Solvents purchased and used in the system should equal solvents "used up" in processing (primarily evaporation) plus solvent wastes disposed of out of the system. The difference between the estimated inflow and outflow of materials is considered an imbalance and potentially lost via the failed tank. Chemicals were brought into the Fairchild South San Jose facility in two ways. They were either sent to that facility from the Fairchild Mountain View facility's Chemical Stores Department or they were purchased directly from chemical vendors. An unknown amount was "used up" or evaporated during the manufacturing process. Solvent wastes were collected in either 55 gallon drums or one of two bulk solvent storage tanks until they were shipped for disposal.

Review of the Fairchild Report

The first step in our analysis of Fairchild's report was to review the report to understand how Fairchild arrived at their conclusions regarding the date the leak began. We needed to know how they calculated the total volume of solvents brought into the facility, the volume of solvents lost through evaporation, and the volume of solvent wastes transported for disposal.

Review of the Original Data Set

The next step was to try to review the original data set used for the MBR. While trying to locate this data set, we learned that the MBR was not prepared by Fairchild staff, but was actually prepared by the law firm of Pillsbury, Madison, and Sutro. From what we were able to learn, data for the report was gathered by Fairchild staff and turned over to the attorneys for analysis and the production of the report. We contacted Pillsbury, Madison, and Sutro to request the original set of data they used to produce the report. We were told that all of the data had been returned to Fairchild, and that their office no longer had any data pertinent to our investigation.

Review of the Fairchild Documents

Since the original data set was not available, we reviewed the documents from which the original data set had been gathered. Fairchild produced hundreds of thousands of documents for litigation purposes. It should be noted that the overall production of documents for litigation took several years, and that potentially more documentation was available to DHS than to the preparers of the MBR. These documents were indexed, boxed, and held in storage. Fairchild allowed us to review the documents at the San Francisco offices of their attorneys, Landels, Ripley, and Diamond (LRD). We began by reviewing the index of these documents in order to identify and request those documents which we felt would be most useful for our purposes. We then reviewed thousands of pages of documents included under the categories of: plant construction, maintenance and operations, chemical usage, government communications, safety and training, corporate safety, management and organization, security logs, remedial program, testing and environmental

policy, insurance, and specific Fairchild managers' files. We also reviewed the deposition of a Fairchild employee familiar with operations.

From our review of these documents, we were able to obtain most of the solvent inflow (including the solvent issues from Mountain View and the solvent purchases from chemical vendors) and the solvent outflow (waste collected and transported for disposal) data. We did not obtain sufficient data to be able to analyze the extent to which chemicals are used up or evaporated during the manufacturing process.

We learned that the failed solvent waste tank was equipped with a gauge to measure the tank's fullness. We were interested in reviewing the logs of these tank gauge readings. The data contained in these logs is an important source of information regarding the rate at which solvent wastes enter the tank. The log is also a record of the amount of solvent which was in the tank at the times it was emptied for waste disposal. Additionally, an analysis of the fill rate of the tank could have shown when the typical fill rate was interrupted, as in the case of a leak.

Fairchild's attorneys provided DHS with one key piece of information regarding glycol ether. Landels, Ripley, and Diamond wrote in a letter to Dwight R. Hoenig of the DHS Toxic Substances Control Division (TSCD) dated December 13, 1984 that Fairchild used a positive photoresist which was a proprietary blend of 70% cellosolve acetate, 10% N-butyl acetate, and 5% xylene. The cellosolve acetate is primarily glycol ether. We hoped to document the quantity of positive photoresist used at Fairchild in order to estimate how much glycol ether might have passed through the failed waste solvent tank.

There were other Fairchild documents and depositions made available to us that could have been useful which we could not review because of time and financial constraints. Overall, however, we feel that we were able to review most of the relevant available data.

Review of Data from Other Sources

We pursued other sources of data to validate and/or augment the data gathered from the Fairchild documents. We considered validating Fairchild's chemical purchases data by contacting their chemical vendors, however, this task would have been too time consuming for the limited scope of our study. We attempted to validate waste manifests in two ways. We made a request to the TSCD in Sacramento for their copies of all manifests for the Fairchild South San Jose facility. We also contacted the waste transport companies for copies of the same manifests. We contacted the California Bay Area Air Quality Management District for any information that they had pertaining to the evaporation of solvents used by Fairchild.

We also pursued another approach to help determine the time that the leak began. Learning more about the mechanism of the tank failure might lead us to some clues as to when it failed. We looked at the failed tank which is held in storage in San Jose, and found that many square cuttings had been removed from the tank. In talking to various people knowledgeable about the incident and involved in the litigation that stemmed from it, we learned that some (if not all) of the parties to the litigation had had an analysis done of the tank.

A physical and chemical analysis of the failed tank could possibly provide the most important data on the timing of its failure and leakage. Therefore we considered several options to find out more about the tank construction specifications and what caused it to fail. We attempted to get voluntary cooperation from the tank manufacturer, Owens Corning Fiberglas (OCF), for their evaluation of the mechanism and the timing of the failure. We asked all the parties to the litigation what they knew about the mechanism of the tank failure. We also asked them if they had done an analysis of the tank, and if they would give us the results of any such analysis. Further, we considered performing a physical and chemical analysis of the tank ourselves and contracting a consultant for an interpretation of that analysis.

The many agency and private contacts we made in our data search are listed in Table 5.1. A summary of the data which we attempted to obtain and that which we did obtain is presented in Table 5.2.

RESULTS

Review of the Fairchild Material Balance Report (MBR)

DHS staff reviewed the Fairchild MBR and found errors, omissions and contradictions which raise questions as to the overall accuracy of this analysis and report. For example, after checking the calculations and figures presented in their tabulations of chemical inflow and waste outflow (Appendices A, B, and C), it is evident that arithmetic errors were made. Some examples follow:

Chemical Inflow Errors:

1) Using Fairchild's own figures in Appendix A, we calculated the total solvent purchases in 1979 to be 18,148 gallons, 172 gallons more than Fairchild's total of 17,976 gallons. This appears to be due to the omission of 172 gallons for "3,5,1 pre-mix" from the overall total for the year. Similar arithmetic errors exist throughout the report. Despite this, the error in the five-year total of solvent purchases is negligible because the errors "balance out."
2) On page A.2 (solvent summary for 1978), the amount of solvent purchased for November and December are exactly the same for each of the nine solvents listed. Although this is possible, we suspect that it may instead be a clerical error. (See Notes, 1)
3) On page 4, methyl alcohol is listed as a "solvent material...used at Fairchild's South San Jose facility and...accounted for in this material balance analysis." In reality, in the solvent summaries which follow (Appendix A), Fairchild failed to list purchases of methyl alcohol. (See Notes, 2)
4) On page A.5, there is an asterisk attached to the column total for "photoresist" materials. The column has listed as its total 4866 gallons; it actually adds to 3143 gallons. If the asterisk is intended to refer to an explanation for this discrepancy, none is included in the report.
5) Fairchild did not include any data to indicate the amount of solvent in inventory at the time of the MBR. Inclusion of solvent inventory would have served to reduce the solvent "imbalance".

Waste Outflow Errors:

6) On page B.2, there are two errors in the addition of the number of drums picked up for disposal. In the 1979 figures, the total number of drums should be 75. The total volume of drummed waste (4,125 gallons) is correct, however. In the 1980 figures, the total number of drums should be 636, and the total volume of drummed waste for that year should be 34,980.
7) On page 2 of the MBR, it is stated that "Small amounts of vapor are inevitably emitted from solvents used in the production process, and these amounts are mixed in with the air. This air from the facility is then scrubbed to purify it before it is emitted into the atmosphere." However, the scrubber effluent is not included anywhere in the MBR. (See Notes, 3)
8) The MBR contains conflicting information concerning the criteria for emptying the tank. Was it regularly emptied, or was it emptied only when it was full? On this issue, the report contradicts itself on pages 6 and 7. On page 6, the report states that the tank was emptied when it reached capacity, whereas on page 7, it states that solvent in the waste tanks and drums is retained until a "removable volume" is accumulated. Furthermore, there is no explanation in the report of how the tank's fullness was measured.
9) In mid-1980 (which is the "estimated" time of the start of the leak), there was a sudden change in the method of solvent disposal. Before mid-1980, the majority of solvent wastes hauled for disposal were from the bulk storage tank. After mid-1980, the majority of solvent wastes were disposed in drums. There is no explanation offered in the MBR for this change.
10) More important for this analysis, the amount of waste hauled away appears to have changed dramatically in mid-1980. Before mid-1980, there were bulk disposals of: 5040 gallons (18 December 1978), 3800 gallons (May 1979), 4958 gallons (3 December 1979), and 4500 gallons (4 May 1980). After that date, the amount of solvent disposed of in bulk is an order of magnitude smaller, eg. 500 gallons, 700 gallons, etc., a radical departure from past practice. There is no explanation. Furthermore, there should be separate disposal figures for the large

("failed") and small solvent tanks after the small tank was installed in mid-1980. (See Notes, 4)

Review of the Fairchild Documents

Chemical Inflow

Because the original data set used for the MBR was unavailable, we began our analysis by reviewing thousands of Fairchild documents produced for litigation. To conduct this review, we attempted to locate the data items used in producing the MBR. The MBR states: "the Material Mass Balance data for this report has been developed from the following sources:

1. Records of chemical issues to the San Jose Facility from the Fairchild Mountain View Central Stores and South San Jose purchase records.

2. Records of solvent waste removal manifests for shipment to an approved disposal site.

3. Empirical measurements of ingoing and outgoing solvents taken during the first quarter of 1982."[6]

The MBR states that for the first several years (1977-1980) that the Fairchild South San Jose facility was operating, chemicals were shipped to that facility from Fairchild's Central Chemical Stores Department in Mountain View. This practice was stopped at an unspecified time in 1981. After that time, chemicals were purchased directly from vendors. The chemical shipments from Mountain View, referred to as "chemical issues," were tabulated on a weekly computer-generated report. We found, reviewed, and tabulated solvents from these reports, titled "Stores Weekly Change Reports," for 1978 (except November and December, which we did not locate), 1979, 1980, and January - March 1981. We did not find or review any chemical issues data for 1977 or for later than March 1981.

In addition to the chemical issues, we reviewed hundreds of purchase order releases which documented the order of chemicals from vendors and the receipt of them at the South San Jose facility on Bernal Road. Solvent purchase data were entered directly from the Fairchild documents into a computerized database management system for editing and analysis. The data items entered into the database are included in Appendix B of this report. Duplicate entries were removed after matching on purchase order release number. About 30% of the documents we inputted were duplicates. We then used the duplicates to check the quality of our key-entry, and found very few errors.

We also edited all of the solvent names, removing all of those known to us to be non-solvents which were incorrectly put in the database. We checked the quantity of each solvent entry, and converted all known quantities to gallons. Unknown quantities were left as zero. We then grouped the solvents according to the eleven categories in the MBR, but found some solvents which we could not categorize. Upon requesting help in categorizing these remaining solvents, we were advised by Fairchild attorneys that it was unlikely that we would be able to get the necessary information to accurately finish the grouping. This is due to the fact that the Fairchild South San Jose facility has not been operating for several years and the remainder of the Fairchild facilities were sold by their former owners, Schlumberger Technology Corporation, last year. Therefore, former employees most likely to know how solvents were grouped for the MBR are no longer available. For this reason, we have presented our tabulation of the solvent issues and purchases by month and year, without regard to the solvent groupings, in Table 5.3.

We could not estimate the quantity of glycol ether Fairchild used because we could not accurately identify all solvents categorized as positive photoresist purchases in 1979-1982. We also found issues of ethylene glycol among the 1978 chemical issues. (See Notes, 5)

<u>Waste Outflow</u>

The waste outflow data we used for our analysis were also found among the Fairchild documents. Fairchild had copies of two types of waste removal

records. The first type, a Waste Hauler Record, is the predecessor to the currently used form, a Hazardous Waste Manifest. Current federal and California state law require the use of the Hazardous Waste Manifest to document the removal, transport, and disposal of hazardous waste from the waste's origin to its final disposal site ("cradle to grave").

We reviewed thousands of Waste Hauler Records and Hazardous Waste Manifests that we found among the Fairchild documents. We selected only those records which documented solvent waste removal for our analysis. We encountered a number of problems in analyzing the hauler records and manifests. All of the documents which were used to compile this report were photocopies, sometimes having been previously reproduced several times. In many cases this made these documents, or parts of the documents, barely legible or illegible. Further, those which were legible occasionally had problems of being self-contradictory. For example, a components section of a manifest would list only solvents, but the description of the waste might be listed as "acid solution," "contaminated soil and sand," and/or "oil." However, without any further information other than the record of manifest itself, we took the description of the components to be most accurate.

Also, six of the manifests listed confusing concentrations of solvents and percentages of water which leads us to believe that some portion of at least these six shipments was water. However, we could not interpret the accurate water content of the shipments because of our inadequate understanding of the conventions used by Fairchild and/or the waste transporter staff when they completed the manifests. The water content of the solvent waste transported for disposal artificially inflates the solvent outflow estimates. If the water content of the wastes manifested could be accurately calculated, it would increase the apparent "imbalance" of the MBR. We have included an example of a Fairchild manifest in Appendix C of this report.

We present our findings in three tables. Table 5.4 is a complete listing of all of the manifests included for our analysis, including all those that Fairchild listed in the MBR and those which DHS found and reviewed. Table 5.5 is a listing of the various problems which were discovered in reviewing

the records and manifests. Table 5.6 lists the differences between what DHS found and what Fairchild presented in the MBR.

Evaporation Analysis

The MBR states on page 2 that "Fairchild employed independent laboratories, using EPA approved methods, to conduct tests to determine what portion of the solvent received by the South San Jose Facility is lost through evaporation. Those tests indicate that evaporation accounts for the dispositon of eleven percent (11%) of all solvent. Such an allowance for evaporative disposition has been included in this study."[7]

DHS reviewed February 1982 emmissions tests reports supplied to us along with the other litigation documents. However, we did not find any corresponding analysis or interpretation of these tests to derive solvent evaporation rates.

Tank Gauge

Although the MBR does not mention it, the failed tank was equipped with a gauge which measured the stored solvent level in gallons. The 1978 and 1981 logs of meter readings for the failed tank were among the Fairchild documents. We requested the 1978 meter readings late in our study, and subsequently did not have time to review them. We were informed by Fairchild's attorneys that according to deponents in the litigation, the 1979 tank readings were never found and 1980 tank level readings were accidently destroyed when an acid waste pipe at the South San Jose facility backed up and spilled on them. We reviewed the log of daily meter readings for 1981 which contained readings for "solvent waste treatment." The first entry in this log is a "0" reading on 1/5/81. The readings average about 500 gallons ± 200 gallons for the first four months of 1981. In May, the readings increase to 900 gallons. In June, the readings decrease and drop to zero on 6/23/81. There is no later non-zero entry for solvent waste in the log. In the entries for October of 1981, question marks "?" appear next to the zero entries, but there is no explanation. Fairchild's attorneys informed us that several Fairchild employees deposed in the South San Jose litigation testified that the solvent tank gauge repeatedly malfunctioned in

1980 and 1981 and was not relied upon as an accurate indicator of the level of solvents in the tank. We found no explanation of this in the documents we reviewed, however, as previously stated, we did not review all of the pertinent Fairchild employee depositions.

Other Data Reviewed

Chemical Usage Validation

We searched for sources which might have data to validate Fairchild's chemical inflow data. The only source from which we obtained any data was the San Jose/Santa Clara Water Pollution Control Plant in San Jose. They have a file for Fairchild South San Jose, which contains some, although incomplete, information. The file has an undated, though presumably pre-1982, Industrial Wastewater Discharge (IWWD) Questionnaire which refers to an attachment list of chemicals stored at the site. This attachment is missing from the file. There is a more complete IWWD Application/Permit dated 10-4-82 which does list quantities of chemicals stored and used per month at the site. The list of chemicals does closely match the MBR, however, the groupings and amounts used per month do not match as closely. Table 5.7 presents a comparison of the data found in the MBR and the SJ/SC WPCP file. It is unfortunate for the purpose of this study that other regulatory agencies did not have similar types of data to be used for validation of Fairchild's chemical usage data.

Waste Manifest Validation

We attempted to validate the Fairchild Waste Hauler Records and Hazardous Waste Manifests in several ways. We requested the documents from the Program Monitoring and Personnel Section of the TSCD in Sacramento. We learned from them that our request would entail a search of 143 boxes containing hundreds of thousands of manifests. These manifests are not grouped by facility, so virtually every document would need to be reviewed. After a trial review of twelve boxes of 1979 documents did not produce any manifests relevant to our analysis, we decided that we could not continue the search within the time and budget limits of our study.

We also contacted International Technology (IT) Corporation and Chemical Waste Management, Inc., both of which hauled wastes from the Fairchild San Jose site. Neither of these companies were able to provide us with the manifests we requested.

Evaporation Validation

Although we were not able to find or review documentation that we would consider to be full documentation for Fairchild's evaporation analysis, we did review pertinent information from the Bay Area Air Quality Management District (BAAQMD). The BAAQMD regulates industrial facilities' ambient air pollution emissions through a permitting process.

The BAAQMD file for Fairchild's South San Jose facility contained brief process descriptions, engineering evaluation reports, applications, and correspondence regarding permitting for the facility's estimated air pollutant emissions. In a letter dated August 15, 1980 from Fairchild to the BAAQMD, Fairchild states "records show that for an average month we use approximately 5900 gallons of acids and 2100 gallons of solvents. Experience has shown that 95% of these chemicals stay in liquid form and 5% are exhausted as fumes."[8] However, a July 1982 Engineering Evaluation by the BAAQMD calculates evaporation rates to be much higher. They calculate evaporation rates based on vapor pressure of each chemical. For solvents typically used at Fairchild, BAAQMD assumed evaporation to be: "Acetone 25%, IPA - 15%, all others (Xylene, HMDS, Photoresist, Resist Strip) - 10%."[9] The evaluation report continues to state, "Furthermore, there is an uncertainty regarding the amount of organic solvent that evaporates. The rate has been estimated by the industry to be 10-11%, but there are no firm records to substantiate this. Source test results that have surfaced are not definitive enough to prove this. Records will be required so input and outgo data can be matched to produce a material balance for organic solvents."[10]

The BAAQMD prepared a report "Emissions From Semiconductor Manufacturing in the Bay Area, April 1987."[11] This report states much higher estimates of

solvent evaporation. For example, for negative and positive photoresist usage, "90% of organic solvent in photoresist and developer evaporates."[12] For solvent cleaning stations, "30% of all chemicals used evaporate."[13]

These varying reports of solvent evaporation, coupled with our inability to find appropriate documentation of Fairchild's evaporation estimates, leads us to conclude that the evaporative loss of 11% of all solvents claimed by Fairchild in their MBR cannot be substantiated. The evaporative loss may be much higher, which would lower the apparent "imbalance" of the MBR.

Comparisons of MBR and DHS Tabulations of Inflow and Outflow

In Table 5.8 we have presented a quarterly comparison of MBR and DHS Tabulations of solvent inflow and outflow. The MBR figures are derived from DHS's corrected tabulations of the MBR Appendices A and B. The DHS figures are derived from Tables 5.3 and 5.4. We did not include 1977 figures in this comparison, because we did not find any data for that year. We did not include evaporation in this comparison because we could not validate Fairchild's estimate of evaporation or calculate an appropriate estimate ourselves.

The results of this comparison are that DHS tabulated more solvent inflow and lesser outflow than the MBR. DHS tabulations show an increasingly larger imbalance than the MBR for all four years. (See Notes, 6 and 7)

Tank Failure Mechanism

The failed tank was a resin-coated fiberglas tank manufactured by Owens Corning Fiberglas (OCF). Its design and engineering specifications were supposed to be compatible with Fairchild's intended use. However, the failure occurred as a degradation from the inside of the tank's resin lining due to the incompatability of the chemicals stored in the tank. An analysis of the tank's specifications and the materials that were stored in the tank should indicate the chemical(s) responsible for its failure.

Four days after Fairchild reported the leaking tank and groundwater contamination to the RWQCB, a RWQCB inspector conducted a site visit to

inspect the tank and the site and to talk with Fairchild about the incident. The report of that visit, dated 12/9/81 states, "3) (The) Solvent tank was fiberglas, buried directly in the soil (bottom of tank [approximately] 12' below grade.) Preliminary indications are that the acetone dissolved through the tank bottom. (An) Owens Corning rep. was on (the) scene earlier and gave that opinion to Fairchild. This tank was supposedly constructed using a special resin to make it acetone resistant."[14]

Because acetone was implicated as the material responsible for degrading the tank, we reviewed the MBR Appendices A.1 - A.5 to see what total acetone purchases were for the years 1977-1981. According to the MBR, acetone purchases equalled 43 gallons in 1977, 395 gallons in 1978, 4055 gallons in 1979, 19850 gallons in 1980, and 15349 gallons in 1981.

It is obviously even more important to know when acetone or acetone wastes were put into the failed solvent waste storage tank, since that is the only way the acetone could have effected any damage to the tank. However, we could not get any direct measurement or information about when acetone went into the tank. So, lacking more direct information, we analyzed the waste manifests that we had collected to see if and when acetone was listed as a waste component. We were particularly interested in knowing when acetone was listed as a waste component on manifests which documented "bulk" waste disposal. "Bulk" differentiates wastes stored in the solvent waste storage tanks from those wastes stored in drums.

In order to deduce which of these bulk disposal records most likely pertained to the failed tank, we considered two things: the amount of waste disposed and the date of the disposal. These factors are important because there were two chemical waste storage tanks used at the Fairchild facility. The first tank, the one that failed, was a large tank (approximately 6000 gallon capacity) installed when the facility was built in 1976. This tank was plumbed to two operating wings of the facility. A second smaller tank (550 gallon capacity) was installed in mid-1980 near the "Chem Mix" building where chemicals were mixed and repackaged for use in the operating wings. This tank was plumbed to drains in the floor of the Chem Mix building.

Chemical spills were washed off of the floor and down these drains with water.

We found that acetone was listed as a waste component on manifests of bulk disposals over 550 gallons on 6/1/79 (reported as May 1979 in the MBR), 9/30/80, 3/18/81, and 12/4/81 . Acetone was also listed on some manifests of drum disposals from 5/3/79 through 6/15/81.

We searched for more information regarding the OCF representative who had come to Fairchild to inspect the failed tank. We learned that this representative had filed a report regarding his findings. The representative was later deposed and the report was made an exhibit to the deposition. We asked LRD for access to this deposition, but they referred us to OCF's attorneys, Sedgewick, Detert, Moran, and Arnold. We contacted this firm, but were ultimately refused access to the deposition.

Next, we contacted OCF directly to request access to the report and deposition. We also requested their expertise in explaining the exact mechanism and possible timing of the failure. OCF did not reply to our request, and they did not give us access to the reports or depositions of any OCF employees.

Physical and Chemical Analysis of the Failed Tank

We requested the results of any analysis done on the failed tank from the RWQCB and each of the litigant's attorneys. The RWQCB had not done a tank analysis. We were told by the attorneys for all the litigants that this was considered attorney work product and subject to attorney-client priviledge. Furthermore, we were informed that there were stipulations in the litigation settlement, which was agreed to by all parties, that information was to remain confidential. Therefore, this information was not released to us.

We considered performing a tank analysis ourselves, however, several knowledgeable contacts held the opinion that the results of such an analysis, done six years after the tank had been out of use, would be inconclusive. Furthermore, the cost of hiring a consultant to interpret the

results of such an analysis was outside the limited budget of this investigation.

DISCUSSION

The DHS analysis of the Fairchild Material Balance Report did not identify enough documentation to provide an accurate estimate of the onset of the Fairchild South San Jose underground tank leak. The analysis was hampered by limited time and money, limited data to support the study, and limited cooperation from the sources who held pertinent data. We believe, however, that the analysis does demonstrate that Fairchild also had inadequate data at the time the MBR was prepared to support an accurate calculation of the solvent imbalance at the end of the five year period under study. Furthermore, the MBR conclusion regarding the timing of the leak appears uncertain in light of DHS's inability to replicate the MBR solvent imbalance although no evidence was found that would appreciably alter that date.

Although the material balance methodology may have been an appropriate approach to use in trying to determine Fairchild's solvent imbalance, the data used to fill in the seemingly simple material balance equation for the MBR is complex and portions were likely interpreted inaccurately. We restate the essential components of the equation as we see it and discuss the data used to support each component to illustrate this point. The equation is: Solvents purchased and used in the system should equal solvents "used up" in processing (primarily evaporation) plus solvent wastes disposed of out of the system.

Solvent Purchase Data

The MBR states that ingoing chemical data was compiled from chemical issues from Mountain View and direct purchases by the South San Jose facility. On page 5 of the MBR, it states, "An additional material input to the facility was batch shipments of photoresist materials from two different vendors to the production group during 1980 and 1981. These shipments were accounted for in the incoming mass balance." The compilation of this data was undoubtedly quite complicated. The MBR tables do not present separate

figures for each of these components. Furthermore, the documentation of how each of these components was compiled is not available from Fairchild.

DHS found documentation for a different total of solvent inflow than reported in the MBR. DHS figures for "issues" and "purchases" data are presented separately in Table 5.3. DHS has included Fairchild's explanation of their interpretation of the differences between the MBR and DHS solvent inflow tabulations in Notes 6 and 7. However, despite Fairchild's explanation, and even if DHS was to make the adjustments to their solvent inflow tabulations suggested by Fairchild, the DHS and MBR tabulations would not be completely reconciled. DHS was using Fairchild documents, and yet the inflow estimates between the two are not equal. We can not conclude what the most accurate estimate would be.

Evaporation

DHS could not validate the 11% evaporation figures used in the MBR. The BAQMD reports which we reviewed did not support that estimate either. The BAQMD data that we presented shows that for many of the solvents used by Fairchild, the evaporation rates are higher than 11%. However, the BAQMD also reports that more data needs to be collected to determine the accurate amount of solvent which evaporates.

Waste Disposal

The MBR states on page 4 that the chemical waste disposal records for the early part of the study period may not have been complete. In fact, DHS did find more solvent disposal manifests than Fairchild did for the MBR. However, DHS's tabulation of the waste manifests resulted in a lower calculation of solvent wastes manifested for disposal. In addition, DHS found that six of the manifests listed a significant portion of the waste to be water. If the water content of the waste shipments could be accurately calculated and subtracted from the total solvent waste disposal figure, it would further reduce the amount of solvent disposed. Consequently, the solvent outflow figures as presented in the MBR and the DHS tabulations are both, most likely, inaccurately high.

The DHS analysis also found other, and possibly more accurate, sources of data which Fairchild could have considered to determine the onset of the tank failure. If the tank gauge readings had been properly kept and analyzed, they would have proven to be an excellent source of data regarding the timing of the tank failure. In fact, the Fairchild spill was the singular event that triggered the development of stricter underground tank monitoring and recordkeeping regulations which were recently mandated by new federal and California state laws.

Additionally, more information could have been developed and presented by Fairchild regarding the solvent waste tank's engineering specifications and chemical incompatibilities which caused it to fail. If acetone did have a significant effect on the degradation of the solvent waste tank's structure, then the degradation could have potentially begun as soon as the tank was put into service. However, there is inadequate public information available on this issue to answer questions regarding the exact mechanism of the tank failure, or to draw any firm conclusions as to when the tank might have failed.

References

1. Epidemiological Studies Section, California Department of Health Services: Pregnancy Outcomes in Santa Clara County 1980-1982: Reports of Two Epidemiological Studies. California State Publications Section Report 7540-958-1301-5, 1985.

2. Fairchild South San Jose Material Balance Report, May 11, 1982.

3. Ibid. p.1.

4. Ibid. p.3.

5. Ibid. p.10.

6. Ibid, p.4.

7. Ibid. p.2.

8. Fairchild letter dated August 15, 1980 found in Bay Area Air Quality Management District files.

9. Bay Area Air Quality Management District, "Fairchild Camera and Instrument Corp., MOS Division, Engineering Evaluation", 7-7-82, p.1.

10. Ibid, p.2.

11. Bay Area Air Quality Management District, Emissions from Semiconductor Manufacturing on the Bay Area, April 1987.

12. Ibid, pp.31-32.

13. Ibid, p.32.

14. Regional Water Quality Control Board, Fairchild Semiconductor, San Jose Discharge of Solvents into the ground, 12/9/81 (from 12/8/81 inspection and conference), pp.3-4.

Notes

The Draft Material Mass Balance Analysis was reviewed by over thirty individuals from regulatory agencies, concerned citizen groups, law firms, consultants, Great Oaks Water Company and Fairchild. We appreciate and thank each of the individuals who gave us their thoughtful review and time in preparing comments to the draft report. We have taken all comments into consideration in our final report.

In particular, Fairchild and their attorneys, Landels, Ripley and Diamond, had extensive comments and new information to add to the draft report. The new information they provided regarding solvent inflow data substantially reduces our confidence in our solvent inflow tabulations as presented in Tables 5.3 and 5.8. However, DHS staff did not have sufficient time or resources before the scheduled release of this report to be able to independently verify all of Fairchild's new information. Therefore, we have included their information in these notes as opposed to removing our original tabulations. All of the comments with quotation marks in these notes are quoted from written comments of Fairchild as transmitted to us through their attorneys, Landels, Ripley and Diamond (LRD). Other non-quoted notes are explained parenthetically. DHS notes follow the Fairchild comments.

1. "The November/December 1978 solvent purchase information was evenly divided between the months because available information at the time of the MBR was for the two month period. Therefore, the November/December 1978 numbers are estimates."

2. Methyl alcohol purchases are probably included with the figures for IPA. (Telephone conversation with LRD attorney).

3. "The Draft Report refers to the MBR's omission of scrubber effluent as a 'waste outflow error.' As was discussed with the Regional Water Quality Control Board in some detail in 1982 the scrubbers at Fairchild's facility were primarily intended to scrub acids from the airstream. To

some extent, incidental solvents may also have been scrubbed from the airstream. The scrubber effluent was discharged to the acid neutralization system at the Fairchild South San Jose facility. Therefore, there was no relationship between scrubber effluent and the amount of solvent which may have reached the failed solvent waste tank."

DHS included its observation that scrubber effluent is not included anywhere in the MBR for two reasons. First, the MBR includes the statement about emissions scrubbing relevant to solvent evaporation. Secondly, Fairchild submitted solvent emissions calculations documents in 1980 and 1982 to the BAQMD in support of their applications for appropriate permitting to operate their South San Jose facility. In 1982, the recommendation that the Permits to Operate be issued to Fairchild was qualified by three conditions. Each of these conditions pertained to the use, emissions scrubbing, and disposal of <u>solvents</u>. Clearly, the issues of solvent evaporation, the efficiency of solvent removal by emissions scrubbing, and the measurement of solvent in scrubber effluent is pertinent to a solvent materials balance analysis. In the Fairchild case, an accurate accounting of solvent in the scrubber effluent would help verify the amount of solvent lost to evaporation and thus further substantiate the estimated amount of solvent which reached and may have leaked from the failed solvent waste tank.

4. "The final 'waste outflow error' noted in the Draft Report is that the Fairchild MBR does not separately state disposal figures for the large ('failed') and small solvent waste tanks after the small tank was installed in mid-1980. Operations people at Fairchild testified at their depositions that there were several occasions when the waste hauler emptied both the large and small solvent waste tanks into a tanker truck after mid-1980 without differentiating the gallonage between the tanks. Therefore, the data which DOHS believes 'should' be available simply is not available."

DHS agrees that if information is simply not available, then that should be clearly stated. The fact that the information was not presented because it was not available is not clearly stated in the MBR. Where

information is available, we believe it should have been included. The exact date of the installation and operation of the Chem Mix 550 gallon tank should be included. The fact that the failed 6000 gallon tank was removed and a new temporary 1000 gallon tank was installed on 12/3/81 should be included. These two pieces of information help define the period when bulk waste disposal figures might have included a combination of the 550 gallon tank and the 6000 gallon tank.

5. "Operational employees from Fairchild repeatedly testified in their depositions that photo resist, in normal operations, would not go down solvent drains to the solvent waste tank but would be disposed of, with stripper materials, by 'super sucker' removal and disposal into drums. Fairchild included photo resist materials in the 1982 MBR because they were part of the incoming and outgoing solvent materials. However, the operational facts concerning the South San Jose facility developed after the MBR was prepared indicate that the likelihood of any substantial quantity of positive photo resist materials reaching the solvent waste tank was remote. Moreover, as acknowledged in the Draft Report, the Bay Area Air Quality Management District estimates that 90% of solvents in photo resist materials evaporate. Therefore, the likelihood of glycol ethers in the solvent waste tank is reduced even further. For the Epidemiological Studies Unit to raise epidemiological concerns about the 'possibility' of a chemical teratogen in groundwater is irresponsible without some substantiation for its concern."

DHS has included information about glycol ethers exactly because of the possibility, however remote, that this chemical teratogen could have reached public drinking water. The operational information about the disposal of photo resists containing glycol ethers into drums that Fairchild attorneys have presented here is very relevant to the interpretation of the MBR, and we are pleased to present it with this analysis.

However, DHS would like to add that this information, along with much other relevant information developed after the preparation of the MBR is not accessable by the public. DHS, in conducting its analysis of the

MBR and making public this report, has sought to disclose new information relevant to the MBR and its conclusions regarding which chemicals in what amounts leaked from the failed tank, and what was the onset and duration of the leak.

6. "<u>DOHS Should Not Include 'Developers' and 'Chrome Etch' as Solvents in its Totals</u>
The Draft Report concludes that there were 42,304 gallons of additional 'incoming' solvents to Fairchild's South San Jose facility from 1978 to 1981 which were not reflected in Fairchild's 1982 Material Balance Report ('the Fairchild MBR'). Of those 42,304 gallons, 37,579 gallons were 'positive developers' and 'chrome etch' (categories 10,23 and 32 in DOHS' backup data). We are informed by former Fairchild employees that those developers (AZ-351; Micro 351, etc.) were alkaline products, <u>not solvents</u>. Therefore, they were disposed of down the acid neutralization system, not in solvent drums or via the bulk solvent waste tank. Similarly, the chrome etch products were acids, not solvents. That information is supported by the enclosed information from chemical suppliers. As you will see, the manufacturers' information confirms the alkaline nature of the positive developer products and the acidic nature of chrome etch. Recommended disposal is by neutralization.

We conclude from the above information that 3,5,1 pre-mix (a developer) should not have been included in the Fairchild MBR as a solvent. This may explain why the only entry for 3,5,1 pre-mix in 1979 (172 gallons) is not added to the solvent totals for 1979 in the Fairchild MBR.

In short, 37,579 gallons of the 'additional solvent purchases' referred to in the Draft Report are <u>not</u> solvents."

DHS includes this important new information from Fairchild in Note 6 as a probable major correction to our solvent inflow calculations presented in Tables 5.3 and 5.8. DHS did not have the resources to independently corroborate this new information presented to us by Fairchild's attorneys before the scheduled release of this report.

DHS staff originally included all three of these chemicals in solvent inflow tabulations for two reasons. These three chemical groups were listed in Fairchild forms titled "Solvent List and Inventory." Also, the 3,5,1 pre-mix, a developer and another developer, 802, were included, perhaps erroneously, as Fairchild points out, in the original MBR.

DHS presented their backup data to Fairchild attorneys upon their request because Fairchild had serious doubts about DHS tabulations presented in the Draft of this report. The DHS tabulations for the three chemicals separately are as follows: 32,453 gallons of AZ-351 and micro 351 developers (DHS category 10); 4886 gallons of projection developer (DHS category 32); and 240 gallons of chrome etch (DHS category 23). The total for all three groups in 37,579 gallons. We have included a copy of the information from chemical suppliers about these three chemicals which Fairchild enclosed in their comments to us as Note 8.

7. "'Drop Shipments' of Chemicals to San Jose

In addition to including non-solvents in its totals, the Draft Report also appears to 'double count' certain solvent purchases in the years 1978 to 1981. As indicated in our April 29, 1988 comments, interviews with former Fairchild employees familiar with the solvent purchase documentation suggest that a number of the purchase orders for solvent materials to South San Jose reviewed by DOHS may have been duplicative of chemicals reflected on the chemical stores reports issued from Mountain View under a master Mountain View purchase order during the years 1978 through mid-1981. We are informed that chemicals, including solvents, were periodically 'drop shipped' by chemical suppliers directly to San Jose under the Mountain View purchase orders. While these 'drop shipments' would create documentation reflecting a direct delivery of chemicals to San Jose, they also would be included in the Mountain View chemical stores reports. Therefore, DOHS may be 'double counting' solvent purchases by recording drop shipments to San Jose both as a 'direct' San Jose purchase and as a 'chemical issue' from Mountain View.

In the short time since receiving DOHS' backup data, we have not been able to locate the underlying data which would allow us to specifically document the extent of any double counting reflected in the Draft Report. However, as an example of the phenomenon, it appears that the Mountain View chemical issues reports for 100% HMDS in 1978 and 1979 would more than account for the 'direct purchases' of 100% HMDS included in the Draft Report backup data. Specifically, the Mountain View chemical issues reflect a total of 145 gallons of 100% HMDS to San Jose in 1978 and 1979. (This total is reflected as part of the 174 gallons of HMDS + 802 in the Fairchild MBR.) The 'direct' purchases of 100% HMDS reflected by DOHS' review of purchase orders total 97 gallons. Therefore, the 'direct' purchases could be merely subsumed within the Mountain View chemical issues reports. While this example is not definitive proof of double counting, it certainly suggests that the information provided by former employees may be correct."

DHS includes this comment from Fairchild as a possible explanation and correction to Tables 5.3 and 5.8. Upon receiving Fairchild's comments on this point, DHS staff re-examined its chemical purchase data, especially with regard to 1978-1980 data. We found 105 purchase order releases for those years, all with the same blanket purchase order agreement number for one vendor. A re-examination of the pertinent 1981 purchase data is more difficult, since Fairchild can not say exactly when in 1981 the method of obtaining chemicals for the South San Jose facility was changed from "chemical issues" by Mountain View to direct chemical purchases by the South San Jose facility.

We were not able to reanalyze the chemical purchase quantities by solvent categories for 1978-1980 before the scheduled release of this report. However, a look at the data reveals that photoresists and 351 developer seem to be the largest volume categories of the chemical purchases for those years. The possible erroneous inclusion of 351 developer has been previously discussed in Note 6.

Although Fairchild believes that the 1978-1980 and early 1981 chemical purchase figures may already be accounted for in the chemical issues data

for the same time period, they can not, as they state in their comments, definitively demonstrate this. Therefore, DHS can not preclude that the documented solvent purchase data for this time period was not additional to the chemical issues data and possibly overlooked in the data compilation phase of the preparation of the MBR.

NOTE 8

November, 1983

351 DEVELOPER
For 1300 Series Positive Photoresist

- ☐ **Wide development latitude**
- ☐ **Compatible with spin/spray develop equipment**
- ☐ **Custom dilutions available**
- ☐ **Compatible with KTI 1300 series photoresist**

KTI 351 Developer in combination with KTI 1300 Series Photoresists is designed to meet the demanding microlithographic and processing requirements of the semiconductor industry. It is an odorless, aqueous, inorganic, alkaline solution, free of phosphates, which is compatible with batch and in-line developing processes. Precise manufacture and stringent quality control ensure batch-to-batch reproducibility and product quality. KTI 351 Developer is supplied as a concentrate. Custom dilutions are also available. The standard High Contrast make-up provides optimum resolution and contrast as well as maximum processing latitude. The Standard High Speed dilution results in very high production throughput. Use of KTI 351 Developer results in reduced bath make-up cost.

Bath Make-Up

To prepare the standard High Contrast and High Speed dilutions from the concentrate, mix KTI 351 Developer and deionized water by volume as follows:

Developer Make-Up	KTI 351 Developer	Deionized Water
High Contrast	1.0 part	5.0 parts
High Speed	1.0 part	3.5 parts

Mix well. Adjust to desired temperature prior to use.

Physical and Chemical Properties

The physical and chemical characteristics are shown in Table 1.

Development

Immersion
Immerse for approximately 60 seconds in either High Contrast or High Speed KTI 351 Developer maintained at a constant temperature (± 1°C) within the range 20°-25°C. Use mechanical or nitrogen burst (not air) agitation. Rinse immediately in deionized water until resistivity is within specifications. Spin dry in air or force dry with filtered nitrogen. Fresh developer gives optimum results. It is recommended that the bath solution be replaced at least once each shift.

Recirculating Bath Spray
Replenish with fresh developer as recommended by the equipment manufacturer.

In-Line Spray
Control developer temperature at the dispensing head at a constant temperature (± 1°C) within the range of 20°-25°C. Moderate spray pressure is recommended. A typical process will involve spraying either the High Speed or High Contrast developer on a slowly spinning wafer for 60 seconds, and overlapping a deionized water rinse with the developing cycle. After a 10-15 second D.I. rinse, the wafer is spun dry.

Table 1

Color	Clear (25 Pt-Co or less)
Turbidity	None (2.0 NTU's or less)
Specific Gravity, 15/25°C	1.083 ± 0.005
*Normality	
Concentrate	1.39 ± 0.05 N
High Speed Make-Up	0.31 ± 0.01 N
High Contrast Make-Up	0.232 ± 0.005 N
Filtration	0.2 μm absolute

*Other dilutions are also available.

KTI 351 Developer **November, 1983**

Determination of Normality

Reagents
Hydrochloric Acid (HCl) 0.2 N. Standardized.
Methyl Red Indicator (0.2% in methanol)

Procedure
1. Pipette 5 ml. of KTI 351 Developer into a 250 ml Erlenmeyer flask
2. Dilute with approximately 100 ml. deionized water.
3. Add 3 drops of methyl red indicator.
4. Titrate with hydrochloric acid (0.2N) to a red endpoint.

Calculation

$$\frac{(\text{ml. HCl}) \times (\text{N HCl})}{5 \text{ ml. KTI 351}} = \text{N of KTI 351}$$

Normality of a freshly made-up batch should be 0.22 to 0.24 N for the standard High-Contrast make-up of 1 part developer with 5 parts deionized water and should be 0.30 to 0.32 N for the High Speed make-up of 1 part developer with 3½ parts deionized water.

Safety Precautions

Handling
HANDLE WITH CARE. KTI 351 DEVELOPER IS AN ALKALINE SOLUTION. IT CONTAINS SODIUM HYDROXIDE. MAY BE HARMFUL IF SWALLOWED. AVOID CONTACT WITH SKIN AND EYES. AVOID BREATHING MISTS. WEAR CHEMICAL GOGGLES, RUBBER GLOVES AND PROTECTIVE CLOTHING.

SPILL OR LEAK: FLUSH SPILL AREA WITH WATER.

First Aid
IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES. CALL A PHYSICIAN. FLUSH SKIN WITH WATER. REMOVE CONTAMINATED CLOTHING AND WASH BEFORE RE-USE.

IF INHALED, MOVE TO FRESH AIR. IF BREATHING HAS STOPPED, GIVE ARTIFICIAL RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN. CALL A PHYSICIAN.

IF SWALLOWED, DO NOT INDUCE VOMITING. GIVE LARGE QUANTITIES OF WATER. NEVER GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. CALL A PHYSICIAN.

Equipment
USE POLYPROPYLENE, POLYETHYLENE, PTFE OR EQUIVALENT MATERIAL. KTI 351 DEVELOPER IS COMPATIBLE WITH MOST ALL COMMERCIALLY AVAILABLE WATER HANDLING EQUIPMENT.

Storage
STORE ONLY IN ORIGINAL CONTAINERS IN DRY AREA AT 50°-90°F (10°-32°C). SEAL CONTAINER WHEN NOT IN USE.

Disposal
DISPOSE OF IN ACCORDANCE WITH LOCAL REGULATIONS. CONTACT YOUR KTI TECHNICAL REPRESENTATIVE IF ASSISTANCE IS REQUIRED.

KTI CHEMICALS INCORPORATED

1170 Sonora Court
Sunnyvale, CA 94086-5385
(408) 733-3500

2125 W. 7th Street
Tempe, Arizona 85281
(602) 968-9212

1200 W. Jackson Road
Carrollton, Texas 75006
(214) 245-5541

2 Barnes Industrial Park Road
Wallingford, Connecticut 06492
(203) 265-9242

UNION CARBIDE
Subsidiary
Union Carbide Corporation
Electronics Division

MICROPOSIT® 351 DEVELOPER

Instructions For Use

I. Bath Make-up

Dilute MICROPOSIT 351 DEVELOPER for use as follows:

	High Speed Make-up (22% solution)	High Resolution Make-up (17% solution)
MICROPOSIT 351 DEVELOPER	1 part by volume	1 part by volume
Deionized water	3½ parts by volume	5 parts by volume

Mix thoroughly. Proper dilution can be verified by analysis for normality. See section VII.

Photoresist dissolution rate increases with increasing developer concentration. Maximum resolution is obtained at the lower developer concentration where unexposed resist loss is minimized. Shorter exposure times are possible when the higher developer concentration is used.

Production line downtime and potential dilution errors can be avoided with ready to use developers (MICROPOSIT 352, 353, 354, 355 DEVELOPERS).

352 is recommended for high resolution (equivalent to 1:5 make-up above).

354 is recommended for high speed (equivalent to 1:3½ make-up above).

II. Temperature

Operate MICROPOSIT 351 DEVELOPER between 20° and 25°C, with the temperature controlled ±1°C. The photoresist dissolution rate increases with increasing developer temperature.

In spray equipment, the spray action causes a temperature drop in the developer solution. For this reason, developer temperature should be monitored at the substrate surface.

III. Time

Immersion: 40–60 seconds.

Spin/spray: Varies with equipment. Consult your Shipley Technical Sales Representative.

Longer development times permit the use of shorter exposure times. Shorter development times minimize developer attack on the unexposed photoresist. The range recommended is optimum. We recommend keeping the development time constant and adjusting the exposure time as necessary to meet critical dimension requirements.

IV. Agitation

Immersion: Mild, consistent agitation is recommended.

Spin/spray: Contact your Shipley Technical Sales Representative.

V. Rinse

Immersion: Cascade rinse with deionized water to resistivity specification immediately after developing.

Spin/spray: Overlap deionized water rinse with developer cycle to prevent developer drying on substrate surface. Provide adequate rinsing of back side of substrates.

VI. Bath Control

Immersion: For maximum process control, replace bath with fresh developer solution at least once per shift. Keep bath covered when not in use.

Spin/spray: Not applicable.

Batch spray: As recommended by equipment manufacturer.

VII. Determination of Total Alkaline Normality

A. Reagents
1. Hydrochloric acid (HCl), 0.1 N, standardized
2. Methyl red indicator solution

B. Procedure
1. Pipette 5 mls aliquot MICROPOSIT 351 DEVELOPER bath into a 250 ml Erlenmeyer flask.
2. Add approximately 100 mls deionized water
3. Add 3 to 5 drops methyl red indicator.
4. Titrate with 0.1 N HCl from yellow to red color change.

C. Calculations

$$\frac{\text{ml HCl titrated} \times \text{N HCl}}{5 \text{ mls}} = \text{Normality of MICROPOSIT 351 DEVELOPER}$$

D. Results

The normality of freshly made-up MICROPOSIT 351 DEVELOPER should be:

1:3½ make-up	0.31 ± 0.02 N
1:5 make-up	0.23 ± 0.02 N

Equipment

Use polypropylene, polyethylene, polytetrafluoroethylene, or equivalent materials.

Storage

Store only in original containers in dry area at 50°–90°F (10°–32°C). Do not store in sunlight. Close container when not in use. MICROPOSIT 351 DEVELOPER has a limited shelf life.

Disposal

MICROPOSIT 351 DEVELOPER should be disposed of according to Shipley Waste Treatment Procedure WT 77-1 (pH adjustment with sulfuric acid). Contact your Shipley Technical Sales Representative for details.

Properties As Delivered

MICROPOSIT 351 DEVELOPER is manufactured to the highest quality standards and is subjected to state of the art testing for physical, chemical and functional properties to assure the user of maximum lot to lot reproducibility.

MICROPOSIT 351 DEVELOPER is filtered to 0.2µm absolute directly into clean containers.

Certificates of Analysis will be supplied with each shipment upon request. Quality Assurance Material Specifications and Analytical Testing Procedures may be obtained upon request from your Shipley Technical Sales Representative.

MICROPOSIT 351 DEVELOPER, as delivered, will conform to the following specifications:

Specific gravity at 20/20°C	1.073–1.093
Color	Water white to very pale yellow solution
Turbidity	Nonturbid
Total Alkaline Normality	1.36–1.42

Handling Precautions

Warning! Dilute sodium hydroxide solution. Harmful if swallowed. May cause burns. Avoid contact with skin and eyes. Avoid breathing mist or spray Handle with care. Wear chemical goggles, rubber gloves, and protective clothing. Material Safety Data Sheet available upon request.
Due to the nature of MICROPOSIT 351 DEVELOPER, disposal of it, or residues therefrom, should be made in compliance with federal, state, and local environmental laws.

First Aid:

If swallowed — contact physician at once.
If eye contact — flush with water for 15 minutes, contact physician.
If skin contact — flush with water for 15 minutes.
If inhaled — move into fresh air.

Spills: Flush with large amounts of water into waste treatment system.

File No. WT77-1

WASTE TREATMENT

Date 6/9/78

WASTE TREATMENT OF SHIPLEY COMPANY PHOTORESIST DEVELOPERS IN USE WITH MICROELECTRONICS

** 1. Adjust pH to 5.0 - 5.5 with Sulfuric Acid (H_2SO_4).

2. Let stir for 30 minutes.

3. Allow precipitate to settle.

4. Decant and filter.

5. Adjust pH to acceptable municipal levels for discharge.

6.* Sewer effluent

* Note: Dispose downstream of other metal bearing waste as the chelates if present are still in solution.

** Note: For Remover 140 substitute for step 1: Dilute with water 3-1 to precipitate dissolved solids.

CHROM-ETCH 1200

U.S. DEPARTMENT OF LABOR
Occupational Safety and Health Administration

Form Approved
OMB No. 44-R1387

MATERIAL SAFETY DATA SHEET

Required under USDL Safety and Health Regulations for Ship Repairing, Shipbuilding, and Shipbreaking (29 CFR 1915, 1916, 1917)

SECTION I

MANUFACTURER'S NAME: Westamerica Chemical Corporation	EMERGENCY TELEPHONE NO.: 415:493-6517
ADDRESS (Number, Street, City, State, and ZIP Code): 716-B San Antonio Ave. Palo Alto, CA. 94303	
CHEMICAL NAME AND SYNONYMS: Chrom-Etch 1200, Chrom-Etch 1200-S	TRADE NAME AND SYNONYMS
CHEMICAL FAMILY: Aqueous Acid solution, corrosive, oxidizer	FORMULA: $(NH_4)_2Ce(NO_3)_6$ + HNO_3 + water

SECTION II · HAZARDOUS INGREDIENTS

PAINTS, PRESERVATIVES, & SOLVENTS	%	TLV (Units)	ALLOYS AND METALLIC COATINGS	%	TLV (Units)
PIGMENTS			BASE METAL		
CATALYST			ALLOYS		
VEHICLE			METALLIC COATINGS		
SOLVENTS			FILLER METAL PLUS COATING OR CORE FLUX		
ADDITIVES			OTHERS		
OTHERS					

HAZARDOUS MIXTURES OF OTHER LIQUIDS, SOLIDS, OR GASES	%	TLV (Units)
Nitric Acid approx.	7	2ppm
Ceric Ammonium Nitrate approx.	13	-

SECTION III · PHYSICAL DATA

BOILING POINT (°F.)	> 212	SPECIFIC GRAVITY (H_2O=1)	1.14
VAPOR PRESSURE (mm Hg.) approx	18	PERCENT, VOLATILE BY VOLUME (%) approx	85%
VAPOR DENSITY (AIR=1)		EVAPORATION RATE (ether =1)	< 1
SOLUBILITY IN WATER	complete	pH	< 1
APPEARANCE AND ODOR: orange solution, odor of dilute nitric acid			

SECTION IV · FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (Method used): not applicable	FLAMMABLE LIMITS: not applicable	Lel	Uel

EXTINGUISHING MEDIA: water fog

SPECIAL FIRE FIGHTING PROCEDURES: Self contained breathing apparatus with full facepiece operated in pressure-demand or other positive pressure mode and full body protective clothing.

UNUSUAL FIRE AND EXPLOSION HAZARDS -

SECTION V - HEALTH HAZARD DATA

THRESHOLD LIMIT VALUE
2ppm (Nitric Acid)

EFFECTS OF OVEREXPOSURE
may cause severe eye damage rapidly, and even blindness. causes skin burns and possible deep ulceration. breathing fumes can damage nasal and respiratory tract. swallowing results in severe damage to mucous membranes and deep tissues.

EMERGENCY AND FIRST AID PROCEDURES
eyes- wash immediately with cool water for 15 minutes, get medical attention.
skin- wash promptly with water, get medical attention if irritated.
inhalation- remove to fresh air, give oxygen if breathin is difficult, get medical attention. if swallowed give water, milk of magnesia, get medical attention immediately.

SECTION VI - REACTIVITY DATA

STABILITY			CONDITIONS TO AVOID
	UNSTABLE		avoid contact with wood or porous organic matter
	STABLE	XX	or easily oxidized organic chemicals.

INCOMPATABILITY *(Materials to avoid)*
easily oxidized materials, strong alkalies, reducing agents.

HAZARDOUS DECOMPOSITION PRODUCTS
acid fumes, nitrogen compounds,

HAZARDOUS POLYMERIZATION			CONDITIONS TO AVOID
	MAY OCCUR		
	WILL NOT OCCUR	XX	

SECTION VII - SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED
neutralize with sodium bicarbonate, small spills may then be flushed to sewer if regulations permit. larger spills-pick up on an acid absorbant and dispose of in an approved dump site. Effluent laws take precedence.

WASTE DISPOSAL METHOD
neutralize and flush to drain if regulations permit. if not permitted, send to approved dump site according to legal regulations.

SECTION VIII - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION *(Specify type)*
OSHA approved respirator if tlv (2ppm) is exceeded

VENTILATION	LOCAL EXHAUST	SPECIAL
	as required to maintain exposure below tlv (2ppm)	
	MECHANICAL *(General)*	OTHER

PROTECTIVE GLOVES
acid resistant gloves

EYE PROTECTION
chemical splash goggles and face shield in compliance with OSHA regulations

OTHER PROTECTIVE EQUIPMENT
impervious clothing and boots.

SECTION IX - SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING
store in a cool dry place away from easily oxidized materials. do not use metal containers. do not re-use bottle for storing drinking water.

OTHER PRECAUTIONS

Table 5.1

Material Balance Report Analysis
Data Sources and Contacts
(Data requested in parentheses)

Agencies

1. Department of Health Services, Toxic Substances Control Division, Sacramento and Emeryville (waste manifests)

2. Bay Area Regional Water Quality Control (background of MBR)

3. Bay Area Air Quality Management District (evaporation data)

4. San Jose/Santa Clara Water Pollution Control Plant (chemical storage data)

Private Companies

1. Owens-Corning Fiberglas, the manufacturer of the failed tank (no data provided)

2. Sedgwick, Detert, Moran, and Arnold, Attorneys for Owens-Corning Fiberglas (no data provided)

3. Landels, Ripley, and Diamond, Attorneys for Fairchild Semiconductor Corporation - Schlumberger Technology Corporation (inflow and outflow data)

4. Pillsbury, Madison, and Sutro, Attorneys for Fairchild Semiconductor Corporation who prepared the Material Balance Report, May 11, 1982. (no data provided)

5. The Boccardo Law Firm, Attorneys for citizen plaintiffs in litigation against Fairchild, Owens Corning Fiberglas, etc. (no data provided)

6. Great Oaks Water Company (background of MBR)

7. IT Corporation, Waste Haulers for Fairchild (waste manifests; not available)

8. Chemical Waste Management, Inc., Waste Haulers for Fairchild (waste manifests; not available)

Table 5.2

Data Items Required for Materials Balance Analysis

Data Item	Why Data Needed	Source	Percent Obtained
Chemical Inflow			
Chemical issues	estimate inflow	LRD	75%
Chemicals purchased	estimate inflow	LRD	90%
Chemicals stored	validate inflow	SJ/SC	100% (1982)
Waste Outflow			
Waste manifests	estimate outflow	LRD	All requested
	validate outflow	DHS-TSCD	All requested
Evaporation	estimate outflow	LRD	not available
	validate outflow	BAQMD	summary only
Tank gauge data	validate outflow	LRD	1981 only
Auxilary Data			
Tank analysis	estimate time of failure	litigants	not available
Acetone	estimate time of failure	litigants	not available

Table 5.3
DHS Tabulations of Solvent Issues and Purchases
by Month and Year[a]

	J	F	M	A	M	J	J	A	S	O	N	D	WHOLE YEAR
Issues	691	900	763	691	382	636	802	603	1700	1974	NA	NA	9142
Purchases	204	48	128	297	199	319	221	280	204	180	300	100	2480
Total 1978	895	948	891	988	581	955	1023	883	1904	2154	300	100	11622
Issues	1361	1355	1552	1312	1592	1218	416	1050	2034	2039	1113	1904	16946
Purchases	24	1008	710	929	1024	750	856	680	738	276	NA	NA	6995
Total 1979	1385	2363	2262	2241	2616	1968	1272	1730	2772	2315	1113	1904	23941
Issues	2129	2466	3844	3031	1172	1602	3717	4312	8859	5489	6275	6123	49019
Purchases	NA	NA	NA	1310	1036	572	1742	2022	2076	1908	NA	112	10778
Total 1980	2129	2466	3844	4341	2208	2174	5459	6334	10935	7397	6275	6235	59797
Issues	3217	3268	4079	NA	NA	NA	NA	NA	NA	NA	NA	NA	10564
Purchases	3212	5193	8786	7262	6127	7752	9557	7085	5593	5527	6907	5372	78373
Total 1981	6429	8461	12865	7262	6127	7752	9557	7085	5593	5527	6907	5372	88937

[a]See Notes 6 and 7 for more information.

Table 5.4
Fairchild Waste Disposal Records

Date	Number	Bulk Volume Gallons	No. of Drums	Gallons Per Drum	Other Quantity Gallons	Total Volume	Confirmed	Problem	MBR Difference
05/31/78	1391	0	23	55	0	1265	y	y	
12/28/78	2329	5040	0	0	0	5040	y		
04/12/79	272e01307	0	46	55	0	2530	y	y	
05/03/79	272e01365	0	19	55	0	1045	y		
06/01/79	08415a	3800	0	0	0	3800	y	y	
08/15/79	11629a	0	30	55	30	1680	y		y
11/05/79	10224sj	400	0	0	0	400	y	y	y
11/15/79	10297sj	0	14	55	0	770	y	y	y
12/03/79	13875a	4758	0	0	0	4758	y	y	
02/04/80	10694sj	0	48	55	0	2640	y	y	
02/15/80	10762Sj	0	8	55	0	440	y		
02/28/80	10822sj	0	39	55	0	2145	y	y	
03/15/80	11287sj	0	83	55	0	4565	y	y	
03/24/80	10848sj	0	19	55	0	1045	y	y	y
05/01/80	11116sj	0	20	55	0	1100	y	y	y
05/05/80	15810a	4500	0	0	0	4500	y		
06/04/80	11349sj	0	38	55	0	2090	y		
06/28/80	16613a	500	0	0	0	500	y		
07/02/80	11533sj	0	18	55	0	990	y		
08/05/80	11621sj	0	17	55	0	935	y		y

Table 5.4 (Continued)

Date	Number	Bulk Volume Gallons	No. of Drums	Gallons Per Drum	Other Quantity Gallons	Total Volume	Confirmed	Problem	MBR Difference
09/05/80	11865sj	0	42	55	0	2310	y		y
09/30/80	19129a	700	0	0	0	700	y	y	
09/30/80	12053sj	0	37	55	0	2035	y	y	y
10/24/80	12374sj	0	97	55	0	5335	y	y	
11/18/80	201142a	0	44	55	0	2420	y		
12/01/80	n/a	700	0	0	0	700	n	y	y
01/09/81	088-022005	0	22	55	0	1210	y		
01/29/81	088-022154	500	0	0	0	500	y	y	y
02/17/81	088-022290	0	39	55	0	2154	y	y	
03/18/81	008-x23533	639	0	0	0	639	y	y	
03/31/81	088-023607	0	39	55	0	2145	y		y
05/01/81	n/a	500	0	0	0	500	n	y	y
06/15/81	088-065131	0	43	55	0	2365	y	y	
09/07/81	088-085645	1595	0	0	0	1595	y	y	y
11/05/81	008-066547	440	0	0	0	440	y	y	y
12/03/81	088-103124	270	0	0	0	270	y	y	
12/04/81	088-2322	580	0	0	0	580	y	y	y
12/12/81	088-016789	500	0	0	0	500	y	y	
12/18/81	008-103027	995	0	0	0	995	y		

Confirmed code: y = DHS did find/ review manifest; n = DHS did not find/review manifest

Problem code: see Table 5.5 problems

MBR Difference code: y = see Table 5.6 MBR Differences

Table 5.5

Problems with Waste Manifests

DATE	NUMBER	PROBLEM
05/31/78	1391	Components illegible
04/12/79	272-e-01307	Components include an unknown quantity of pump oil as well as solvents
06/01/79	08415a	Barely legible volume
11/05/79	10224sj	Confusing concentrations; 55-80% water; also, both acids and solvents in components
11/15/79	10297sj	Kerosene listed as a component
12/03/79	13875a	Volume barely legible
02/04/80	10694sj	Description of components illegible; possibly soil
02/28/80	10822sj	POCl3 listed as a component
03/15/80	11287sj	Illegible record
03/24/80	10848sj	Unknown quantity of oil listed as a component
05/01/80	11116sj	Barely legible volume
09/30/80	19129a	40% water
09/30/80	12053sj	Oil listed as a component
10/24/80	12374sj	Illegible # of drums of HF acid
12/01/80	n/a	Date is actually 12/80 (no day specified in MBR)
01/29/81	088-022154	Oil listed as a component; 80% water
02/17/81	088-022290	75%-97% water
03/18/81	088-?23533	95% water
05/01/81	n/a	Date is actually 5/80 (no day specified in MBR)
06/15/81	088-065131	Components barely legible; illegible quantity of corrosive material
09/07/81	088-085645	Barely legible manifest #, volume, components
11/05/81	088-066547	Barely legible manifest #, volume; components confusing/missing
12/03/81	088-103124	Corresponding IT invoice refers to 088-103124 with volume equal to "five drums"
12/04/81	088-102322	Components barely legible; pickup after larger, failed tank disconnected
12/12/81	088-016789	Day of the month barely legible; 80% water

Table 5.6

MBR/DHS Differences in Interpretation of Manifests

DATE	NUMBER	MBR AMT	DHS AMT	EXPLANATION
08/15/79	11629A	0 drums	30 drums 2 drums	MBR does not list this record
11/05/79	10224SJ	4 drums	400 gal	manifest states 400 gal
11/15/79	10297SJ	25 drums	14 drums	11 drums were empty
03/24/80	10848SJ	22 drums	19 drums	3 drums listed as having contents other than solvents
05/01/80	11116SJ	63 drums	20 drums	43 were HF drums
08/05/80	11621SJ	90 drums	17 drums	73 were HF drums
09/05/80	11865SJ	86 drums	42 drums	44 were HF drums
09/30/80	12053SJ	0 drums	37 drums	MBR does not list this record
12/01/80	N/A	700 gal	700 gal	Unconfirmed; listed in MBR but not found by DHS
01/29/81	088-022154	0 gal	500 gal	MBR does not list this manifest
03/31/81	088-023607	8 drums	39 drums	manifest states 39 drums
05/01/81	N/A	500 gal	500 gal	Unconfirmed; listed in MBR but not found by DHS
06/15/81[a]	088-065132	7 drums	0 drums	Shipment was waste oil--no solvents
09/07/81	088-085645	0 gal	1595 gal	MBR does not list this manifest
11/05/81	088-066547	54 drums	440 gal	manifest states 440 gal
12/04/81	088-102322	0 gal	580 gal	MBR does not list this manifest

[a]Not included on Table 1 waste disposals

Table 5.7

Comparison Between MBR Average
Monthly Solvent Purchases for 1981
and Wastewater Discharge Permit Average
Monthly Solvent Usages for 1982

Solvents	MBR Average Monthly Solvent Purchases (1981)	WWD Permit Average Monthly Solvent Usage (1982)
Acetone	1279	1094
IPA	1065	925
Freon	206	67
Xylene	477	182
1,1,1 TCA	1131	1125
HMDS +802	191	217
Photo-Resist	406	NA
A-30	216	228
J-100	438	745
3,5,1 Premix	0	NA
M-320	0	15

Table 5.8

Quarterly Comparison of Materials
Balance Report with DHS Calculations
(all figures in gallons)[a]

		Solvent Inflow		Solvent Outflow[b]		Difference-Imbalance (Inflow-Outflow)	
	QTR	MBR	DHS	MBR	DHS	MBR	DHS
1978	1	2432	2734	0	0	2432	2734
	2	1581	2524	1265	1265	316	1259
	3	2777	3810	0	0	2777	3810
	4	2898	2554	5040	5040	(-2142)	(-2486)
Total		9688	11622	6305	6305	3383	5317
1979	1	4348	6010	0	0	4348	6010
	2	4068	6825	6330	7375	(-2262)	(-550)
	3	4578	5774	0	1680	4578	4094
	4	5154	5332	6553	5928	(-1399)	(-596)
Total		18148	23941	12883	14983	5265	8958
1980	1	8834	8439	11000	10835	(-2166)	(-2396)
	2	5875	8723	10555	8190	(-4680)	533
	3	17573	22728	11370	6970	6203	15758
	4	18680	19907	8455	8455	10225	11452
Total		50962	59797	41380	34450	9582	25347
1981	1	17014	27755	4434	6639	12580	21116
	2	18137	21141	3250	2865	14887	18276
	3	14951	22235	0	1595	14951	20640
	4	13093	17806	4735	2785	8358	15021
Total		63195	88937	12419	13884	50776	75053
Tot.		141993	184297	72987	69622	69006	114675
		∇ 42304[a]		∇ 3365		∇ 45669[a]	

[a]Please see Notes, 6 and 7 for more information.

[b]Hauled solvent waste only; does not include evaporation.

238.tb8

Appendix A. Fairchild South San Jose Material Balance Report

INTRODUCTION

This material balance report for solvent materials at Fairchild's South San Jose facility was prepared at the request of the Regional Water Quality Control Board. Fairchild has fully cooperated with the Board and other interested public agencies, and has attempted to determine as precisely as possible the extent of the discharge of solvent materials into the ground at the South San Jose facility following the failure of a solvent waste storage tank.

In the theoretical ideal, a material balance is based on the law of conservation of matter; i.e. the total mass of all materials entering a fixed system in a given time must equal the total mass of all materials leaving, plus any accumulation that occurs in the system. However, such precision is attainable only under laboratory conditions.

In the first instance, industrial realities such as time lags between purchase of materials and the use of those materials in production, stock piling, and inventory accumulation tend to exaggerate the volume of materials assumed to be used in production at any particular point in time. Moreover, as practical matter it is impossible to measure the disposition of solvents used in the manufacturing process with one hundred percent (100%) accuracy. For example, some solvent residue remains on surfaces that are cleaned with these

materials; insignificant amounts of water become mixed with solvents from time to time, and small quantities of solvent remain in the "empty" containers in which material was purchased. Thus, when solvent receipts are balanced against solvent removals, a certain quantity of solvent always appears to have been "used up" in the manufacturing process. No allowance for these inherent variances in solvent balance measurements was used in this study. However, information we have received from consultants and public agencies indicates that measurement variances of between five to ten percent (5-10%) are normal, and can be expected.

Another amount of solvent which is "used up" in the manufacturing process is due to evaporative loss. Fresh air is constantly circulated through the production facility. Small amounts of vapor are inevitably emitted from solvents used in the production process, and these amounts are mixed in with the air. This air from the facility is then "scrubbed" to purify it before it is emitted into the atmosphere. During the first quarter of 1982, Fairchild employed independent laboratories, using E.P.A. approved methods, to conduct tests to determine what portion of the solvent received by the South San Jose facility is lost through evaporation. Those tests indicate that evaporation accounts for the disposition of eleven percent (11%) of all solvent. Such an allowance for evaporative disposition has been included in this study.

To evaluate the results of our study of historical data, we attempted to determine the degree of precision which could

be attained in a solvent balance study of current data. We carefully measured all incoming and outgoing solvent during the first quarter (January, February and March) of 1982. A balancing of solvents received against solvent waste removed (plus evaporation) during this period accounted for the disposition of only ninety-six percent (96%) of the total solvent for that quarter. The results in this study are based on an exhaustive review of current data, and support the view that solvent balance measurements are, at best, imperfect and that a variance of up to ten percent (10%) is to be expected.

METHODOLOGY

The present material mass balance focuses on solvents and solvent-based chemicals used in semiconductor manufacturing operations at Fairchild's South San Jose Facility. These materials are used in general cleaning within the facility as well as in the manufacturing processes of wafer cleaning, wafer inspection, wafer coating, wafer etching, and wafer spinning.

The following solvent materials are used at Fairchild's South San Jose facility and are accounted for in this material balance analysis:

A-30 (photoresist remover)

Acetone

Isopropyl alcohol (IPA)

Freon

Hexelmethyldisilane (HMDS)

J-100 (photoresist remover)

Markham 320 Cleaner

Methyl alcohol

3.5.1 Pre-mix

Photoresist material

1, 1, 1 Trichloroethane (TCA)

Xylene

The material mass balance data for this report has been developed from the following sources:

1. Records of chemical issues to the San Jose Facility from the Fairchild Mt. View Central Stores and South San Jose purchase records.
2. Records of solvent waste removal manifests for shipment to an approved disposal site.
3. Empirical measurements of ingoing and outgoing solvents taken during the first quarter of 1982.

The period for which this material mass balance was conducted is January 1977 through December, 1981; i.e. from the opening of the facility until the detection and replacement of the defective solvent waste tank. The data set forth herein accurately reflects all of Fairchild's records. However, chemical waste disposal for the first part of this period may not be complete. While all of Fairchild's records were thoroughly reviewed, we were unable to complete an equally thorough

review of the files of certain public agencies and haulers of chemical waste.

INCOMING CHEMICALS

As the first step in establishing the material balance for solvents it was necessary to examine all sources of material inputs to the Fairchild South San Jose facility. In the beginning of the period of study in 1977, chemicals were shipped to the South San Jose facility from Fairchild's Central Chemical Stores Department in Bldg. 9, Mt. View. All of these shipments were tabulated on a weekly report.

An additional material input to the facility was batch shipments of photoresist materials from two different vendors to the production group during 1980 and early 1981. These shipments were accounted for in the incoming chemical mass balance.

In 1981, Fairchild stopped shipping chemical materials to San Jose from its Mt. View facility. Instead, chemicals were purchased by San Jose directly from vendors. San Jose purchasing records were used to compile information in this report on chemical shipments from 1981 to the present.

Finally, another input taken into consideration was small amounts of materials brought into the facility by manufacturers representatives for demonstration purposes. These quantities were insignificant and, therefore, were not used in determining the overall mass balance.

Included in Appendix A are lists of all solvent received by the South San Jose facility from 1977 through 1981. These receipts are broken down by month and by the type of solvent received.

OUTGOING CHEMICALS

There are three methods by which waste solvents are collected for disposal. These methods are:

A. Bulk Solvent Tank (Large): The Fairchild building production areas are equipped with a waste solvent drain collection system. Certain sinks are reserved for solvent disposal; no acid waste and no water other than small amounts mixed with solvent waste is placed in them. Solvent waste is then piped from the sinks to a holding tank. The tank is emptied by tanker trucks when it reaches capacity. Until December 1981, when the tank was discovered to have failed, the solvents from Wing A and Wing B were collected in a 6000 gallon solvent waste tank. That tank has since been replaced with a temporary 1000 gallon solvent waste tank. This tank is being used pending the installation of a new permanent tank which is to be enclosed in a concrete vault.

B. Bulk Solvent Tank (Small): The small bulk solvent tank is located near the Chem Mix building to collect waste solvent from that area. It has a capacity of approximately 550 gallons. Like the larger solvent tank, the small tank is emptied when full by a tanker truck. The Chem Mix Building is

equipped with a solvent waste drain which is connected to this tank.

C. Drum Solvents: Certain solvent waste is also collected at various points in the production process in portable seven-gallon tanks. The seven-gallon tanks are mounted on rolling carts, taken to the Chem Mix Building and emptied into 55 gallon drums. These drums are periodically removed by a licensed hauler of chemical waste.

Included as Appendix B are tables showing the dates and volumes of solvent materials removed from the South San Jose facility. These tables were prepared from shipping manifests and the records of licensed haulers of chemical waste.

CORRELATION OF SOLVENT USAGE TO SOLVENT REMOVAL

Correllation or balancing of solvent purchase data with waste removal data is difficult for at least two reasons. First, solvent is purchased substantially in advance of the time it is employed in the production process. Second, waste solvent is not removed every month. Solvent accumulations in the waste tanks and solvent waste drums are retained until a removable volume is accumulated. Thus, removal of any gallon of solvent tends to take place long after that gallon of solvent was purchased.

To correct for this disparity, we attempted to determine the time at which solvents were accumulated for disposal. For

example, in May, 1978, 1265 gallons of waste solvent were removed in drums. (See Appendix C, p. 1.) The next removal of solvent in drums occurred in April, 1979. However, some portion of the 2530 gallons removed in April, 1979 was accumulated during 1978 (after the May removal of waste solvent in drums). To determine what that portion was, the period between removal is measured (11 months) and the volume of the April, 1979 removal is divided by the number of months during the period (2530 ÷ 11 = 230). Seven months of the solvent waste removed in April, 1979 should be attributed to June - December, 1978. Thus, 1,680 (7 x 230) is added to 1,265 and the total solvent drum waste for 1978 is determined to be 2,875.

Similarly, solvent purchases tend to vary markedly from month to month. To determine the representative level of solvent usage for each quarterly period, a three month moving average was calculated. Such an average yields the number of gallons of solvent used in a "normal" month during that quarterly period. (The statistician's worksheet for this calculation is included in Appendix C, p. 3.)

When the results of these two calculations are compared, there is a strong correlation between quarterly solvent receipts and quarterly solvent removals until mid-1980. Solvent removals consistently increase in relation to increases in solvent receipts through the second quarter of 1980. Thereafter, solvent receipts increase markedly and solvent removals begin to diminish. (A graph illustrating this relationship is

presented in Appendix D, p. 2.) Thus, such a comparison tends to indicate that the solvent waste tank failed sometime after mid-1980.

The graph presented in Appendix D, p. 3 illustrates the cumulative difference in gallons between total solvents received and total solvent dispositions (removals plus evaporation). Note that the cumulative difference decreases in the first and second quarters of 1980 because the solvents removed during those two quarters exceeded the solvents received (i.e. solvents received in earlier quarters were used and disposed of in the first half of 1980). After mid-1980, the cumulative difference between receipts and dispositions markedly increases. Thus, this comparison further tends to indicate that the solvent waste tank failed sometime after mid-1980.

CONCLUSIONS

When records of solvent receipts are "balanced" in the manner described above against records of solvent disposals, the end result is that until mid-1980 essentially all of the solvent used at Fairchild's South San Jose facility can be accounted for. From the date the facility opened until mid-1980, 46,371 gallons of solvent were purchased. Of that total, only 1,139 gallons were 1,1,1 TCA, and the majority of that was purchased in the first half of 1980. (See Appendix C.4.)

From mid-1980 until the discovery and replacement of the defective solvent waste tank in December, 1981, 102,446 gallons of solvent (including 13,956 gallons of 1,1,1 TCA) were received by the South San Jose facility. We are able to account for the disposition of forty-three percent (43%) of this material. Thus, the maximum number of gallons of solvent which may have been lost appears to be 58,394 (102,446 x .57).

Thus, within the accuracy parameters already explained, all solvent used at Fairchild's South San Jose facility can be accounted for until mid-1980. After mid-1980, an apparent imbalance occurs. On December 4, 1981, the failure of the solvent waste tank was discovered. Solvent receipts and disposals returned to a "balanced" status in January 1982. The data, therefore, tends to indicate that the solvent waste tank failed, at the earliest, after mid-1980.

APPENDIX A

SOLVENT RECEIPTS

1977 - 1981

1977 SOLVENT SUMMARY (PURCHASES)

	ACETONE	IPA	FREON	XYLENE	1,1,1 TCA	HMDS + 802	xylene, acetate PHOTO RESIST	PCE, DC benzene, phenol, TC benzene A-30	PCE, DC benzene, phenol, TC benzene J-100	3.5.1 PRE-MIX	IPA, acetate MARKHAM 320		
JANUARY													
FEBRUARY													
MARCH	1	25	2	39	1	4	9						
APRIL		6	12	10		4	0	10					
MAY		4	5				0						
JUN	12	32	76	60	6		4						
JULY		18	8	16			10						
AUGUST		99		76	35		8	12					
SEPTEMBER		128	118	96	8		20	80					
OCTOBER							28						
NOVEMBER	12	50	8	122	12		28						
DECEMBER	18			91		12	20	32	8				
TOTAL	43	362	229	510	62	20	127	134	8				

OTAL SOLVENTS = 1,471 GALLONS
OTAL 1,1,1 TCA: 62 GALLONS

Appendix A.1

1978 SOLVENT SUMMARY (PURCHASES)

	ACETONE	IPA	FREON	XYLENE	1,1,1 TCA	HMDS + 802	PHOTO RESIST	A-30	J-100	3.5.1 PRE-MIX	MARKHAM 320		
JANUARY	0	131	55	273	18	2	144	0	32				
FEBRUARY	60	195	165	175	36	12	193	0	64				
MARCH	0	218	55	515	0	4	32	47	0				
APRIL	0	150	110	348	0	8	20	1	20				
MAY	18	74	0	253	0	1	12	4	0				
JUNE	10	134	55	324	0	4	28	7	0				
JULY	36	249	110	291	0	0	0	60	0				
AUGUST	35	142	110	160	0	8	0	32	40				
SEPTEMBER	53	328	440	292	0	8	0	355	28				
OCTOBER	117	360	0	648	11	0	28	94	24				
NOVEMBER	33	198	110	328	7	5	46	60	21				
DECEMBER	33	198	110	328	7	5	46	60	21				
TOTAL	395	2377	1320	3941	79	57	549	720	250				

TOTAL SOLVENTS = 9,688 GALLONS

TOTAL 1,1,1 TCA: 79 GALLONS

Appendix A.2

1979 SOLVENT SUMMARY (PURCHASES)

	ACETONE	IPA	FREON	XYLENE	1,1,1 TCA	HMDS + 802	PHOTO RESIST	A-30	J-100	3.5.1 PRE-MIX	MARKHAM 320		
JANUARY	320	640		490	55			2			12		
FEBRUARY	288	108	55	648		4	22		108	112	10		
MARCH	440	260	165	72		72	22	288	108	38	9		
APRIL	330	236	111	569							12		
MAY	440	433	110	381				108	108		12		
JUNE	110	368	165	436		21		4	108		6		
JULY	379	396	55	597	55						12		
AUGUST	330	216	55	327			4	108			10		
SEPTEMBER		612	330	523	163			288	108		10		
OCTOBER	440	361	660	362				144			12		
NOVEMBER	648	300	110	165			16			22	10		
DECEMBER	330	540	110	438	54	30		288	108		6		
TOTAL	4055	4470	1926	5008	327	127	64	1230	648	172	121		

TOTAL = 17976 GALLONS

TOTAL 1,1,1 TCA: 327 GALLONS

Appendix A.3

1980 SOLVENT SUMMARY (PURCHASES)

	ACETONE	IPA	FREON	XYLENE	1,1,1 TCA	HMDS + 802	PHOTO RESIST	A-30	J-100	3.5.1 PRE-MIX	MARKHAM 320		
JANUARY	155	768	0	766	110	48		252	0		16		
FEBRUARY	220	1045	400	546	110	0		0	144		15		
MARCH	605	1216	330	1143	491	4		440	0		0		
APRIL	1135	432	220	746	0	0	6	144	324		46		
MAY	0	648	0	216	0	0	22	288	0		20		
JUNE	550	328	2	432	0	0	24	292	0		0		
JULY	1080	1080	120	923	0	0	66	288	216		20		
AUGUST	1784	756	490	1239	221	0	89	144	0		20		
SEPTEMBER	4256	2333	265	1469	165	0	81	432	0		36		
OCTOBER	2911	2166	130	0	0	0	137	288	0		14		
NOVEMBER	3714	1538	55	1186	0	0	40	144	108		30		
DECEMBER	3430	1182	165	764	0	0	96	432	108		42		
TOTAL	19850	13492	2177	9430	1097	52	561	3144	900		259		

TOTAL SOLVENTS = 50,962 GALLONS

TOTAL 1,1,1 TCA: 1,097 GALLONS

1981 SOLVENT SUMMARY (PURCHASES)

	ACETONE	IPA	FREON	XYLENE	1,1,1 TCA	HMDS + 802	PHOTO RESIST	A-30	J-100	3.5.1 PRE-MIX	MARKHAM 320		
JANUARY	1255	1548	55	165	0			0	144				
FEBRUARY	1006	1083	385	220	605	20	120	576	324				
MARCH	2418	2509	275	1406	1650	232	480	430	108				
APRIL	990	935	275	685	1320	276	448	144	0				
MAY	990	1065	330	1045	825	124	355	144	216				
J[illegible]	1815	1630	275	1045	2145	228	328	288	216				
JULY	1210	660	220	110	755	316	280	288	216				
AUGUST	1320	880	385	715	1870	196	200	144	648				
SEPTEMBER	1265	660	55		1210	248	308	144	648				
OCTOBER	1110	440	110	110	1100	240	284	144	1440				
NOVEMBER	990	825	110	110	1320	272	292	144	432				
DECEMBER	990	550		110	770	144	48	144	864				
TOTAL	15349	12785	2475	5721	13570	2296	4866	2592	5256				

TOTAL SOLVENTS = 64,910 GALLONS
TOTAL 1,1.1 TCA: 13,570 GALLONS

Appendix A.5

APPENDIX B

SOLVENT WASTE DISPOSALS

1977 - 1981

WASTE BULK SOLVENT SHIPPED FOR DISPOSAL

1978

Date		Volume/Gallons	Manifest No.
12/18/78		5,040	2329

1979

Date		Volume/Gallons	Manifest No.
May, 1979		3,800	(12/9/81 Correspondence from I.T. Corporation)
12/3/79		4,958	13875
	Total	8,758	

1980

Date		Volume/Gallons	Manifest No.
5/5/80		4,500	15810
6/28/80		500	16613
9/30/80		700	19129
Dec. 1980		700	(12/9/81 Correspondence from I.T. Corporation)
	Total	6,400	

1981

Date		Volume/Gallons	Manifest No.
3/18/81		639	088-023533
May 1981		500	(12/9/81 Correspondence from I.T. Trans)
12/03/81		270	088-103124
12/15/81	(Date Unclear)	500	088-016789
12/18/81		995	088-103027
	Total	2,904	

SOLVENT DRUM PICKUP

1978

Date		55 Gal Drums	Manifest No.
5/31/78		23	1391
	Total	23	
		x 55	
		1,265 Gal.	

1979

Date		55 Gal Drums	Manifest No.
4/12/79		46	01307
11/15/79		4	10224
11/15/79		25	10297
	Total	71	
		x 55	
		4,125 Gallons	

1980

Date		55 Gal Drums	Manifest No.
2/4/80		48	10694
2/15/80		8	10762
2/28/80		39	10822
3/15/80		83	11287
3/26/80		22	10848
5/01/80		63	11116
6/04/80		38	11349
7/02/80		18	11533
8/05/80		90	11621
9/05/80		86	11865
10/24/80		97	12374
11/18/80		44	201142A
	Total	673*	
		x 55	
		37,015 Gallons	

1981

Date		55 Gal Drums	Manifest No.
1/09/81		22	988-022005
2/17/81		39	088-022290
3/31/81		8	088-023607
6/15/81		43	088-065131
6/15/81		7	088-065132
11/5/81		54	088-066547
	Total	173	
		x 55	
		9,515 Gallons	

* Includes a small number of empty hydroflouric acid drums.

APPENDIX C

STATISTICAL WORKSHEETS

		WASTE BULK				WASTE DRUMS				
		GAL	AVG PER MONTH	AVG RUN RATE PER QRT	CUM	GAL	AVG PER MONTH	AVG RUN RATE PER QRT	CUM	TOTAL CUM
	Jan		420				253			
	Feb		420				253			
	Mar		420	420	1260		253	253	759	2019
	April		420					253		
	May		420			1265	253			
	June		420	420	2520		230	245	1494	4014
1978	July		420				230			
	Aug		420				230			
	Sept		420	420	3780		230	230	2184	5964
	Oct		420				230			
	Nov		420				230			
	Dec	5040	420	420	5040		230	230	2874	7914
	Jan		760				230			
	Feb		760				230			
	Mar		760	760	7320		230	230	3564	10884
	April		760			2530	230			
	May	3800	760				228			
	June		708	743	9548		228	229	4251	13799
1979	July		708				228			
	Aug		708				228			
	Sept		708	708	11672		228	228	4935	16607
	Oct		708				228			
	Nov		708			1595	228			
	Dec	4958	708	708	13796		1742	733	7134	20930
	Jan		900				1742			
	Feb		900			5225	1742			
	Mar		900	900	16496	5775	5775	3086	16392	32888
	April		900				1733			
	May	4500	900			3465	1733			
	June	500	500	767	18796	2090	2090	1852	21948	40744
1980	July		233			990	990			
	Aug		233			4950	4950			
	Sept	700	233	233	19496	4730	4730	3557	32619	52115
	Oct		233			5335	5335			
	Nov		233			2420	2420			
	Dec	700	233	233	20196		605	2787	40980	61176

Appendix C.1

		WASTE BULK				WASTE DRUMS				
		GAL	AVG PER MONTH	AVG RUN RATE PER QRT	CUM	GAL	AVG PER MONTH	AVG RUN RATE PER QRT	CUM	TOTAL CUM
	Jan		213			1210	605			
	Feb		213			2145	2145			
	Mar	639	213	213	20835	440	400	1050	44130	64965
	April		250				917			
	May	500	250				917			
	June		252	251	21587	2750	917	917	46881	68468
1981	July		252				594			
	Aug		252				594			
	Sept		252	252	22343		594	594	48663	71006
	Oct		252				594			
	Nov		252			2970	594	594	49851	
	Dec	1765	252	252	23099		594			72950

SOLVENTS RECEIVED

		Moving Avg. (3)		Sum by Quarter	CUM
	Jan				
	Feb				
	Mar	81			
	April	42	44		
	May	9	80		
	June	190	84	208	208
1977	July	52	157		
	Aug	230	244		
	Sept	450	236	637	845
	Oct	28	237		
	Nov	232	147		
	Dec	181	358	742	1587
	Jan	661	581		
	Feb	900	811		
	Mar	871	809	2201	3788
	April	657	630		
	May	362	527		
	June	562	557	1714	5502
1978	July	746	608		
	Aug	517	922		
	Sept	1504	1101	2631	8133
	Oct	1282	1198		
	Nov	808	966		
	Dec	908	1045	3209	11342
	Jan	1519	1227		
	Feb	1355	1449		
	Mar	1474	1362	4038	15380
	April	1258	1441		
	May	1592	1356		
	June	1218	1435	4232	19612
1979	July	1494	1254		
	Aug	1050	1526		
	Sept	2034	1688	4468	24080
	Oct	1979	1761		
	Nov	1271	1718		
	Dec	1904	1864	5343	29423
	Jan	2418	2365		
	Feb	2773	3238		
	Mar	4522	3545	9148	38571
	April	3340	3109		
	May	1465	2234		
	June	1897	2461	7804	46375
1980	July	4020	3621		
	Aug	4947	6072		
	Sept	9249	6666	16359	62734
	Oct	5802	7373		
	Nov	7068	6432		
	Dec	6426	5562	19367	82101
	Jan	3191	4693		
	Feb	4461	5760		
	Mar	9628	6501	16954	99055
	April	5413	6760		
	May	5240	6263		
	June	8135	5839	18862	117917
1981	July	4143	6274		
	Aug	6543	5140		
	Sept	4734	5387	16801	134718
	Oct	4883	4787		
	Nov	4743	4474		
	Dec	3796	4842	14103	148821
	Jan	5987	5132		
1982	Feb	5613	6356		
	Mar	7468	5599	17087	165908

SOLVENT USED v. SOLVENT DISPOSITIONS
(IN GALLONS)

Year	Solvents Used* Total Solvents Used	(TCA)	Solvents Removed** Drums	Bulk	Evaporation	Total Out
1977	1,587	62	Ø	Ø	175	175
1978	9,755	79	2,875	5,040	1,073	8,988
1979	18,081	327	4,260	8,757	1,989	15,004
1/80 - 6/80	16,952	671	14,814	5,001	1,865	21,680
7/80 - 12/80	35,726	386	19,032	1,398	3,930	24,360
1981	66,720	13,570	9,465	2,904	7,339	19,708

Year	Solvents Used* Total Solvents Used	(TCA)	Solvents Removed** Drums	Bulk	Evaporation	Total Out	%Δ
1982	19,068	3,614	6,750	9,425	2,097	18,272	4%
SUBTOTAL 1977-Mid-1980	46,371	1,139	21,949	18,798	5,102	45,849	1%
SUBTOTAL mid-80-12/81	102,446	13,956	28,497	4,302	11,269	44,068	57%

* Based on three-month moving average of solvents received

** Based on date solvent accumulated for removal.

APPENDIX C.4

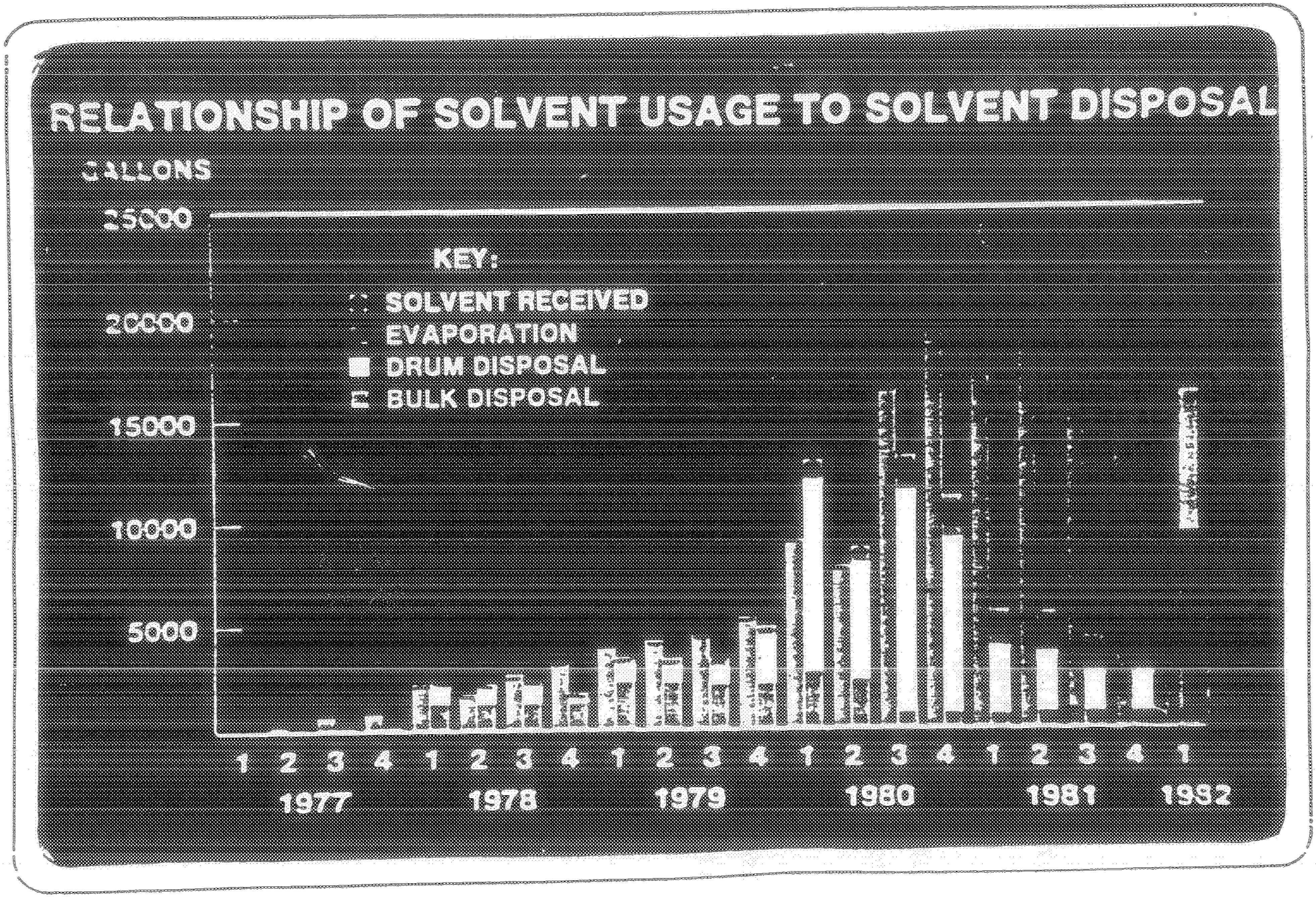
APPENDIX D

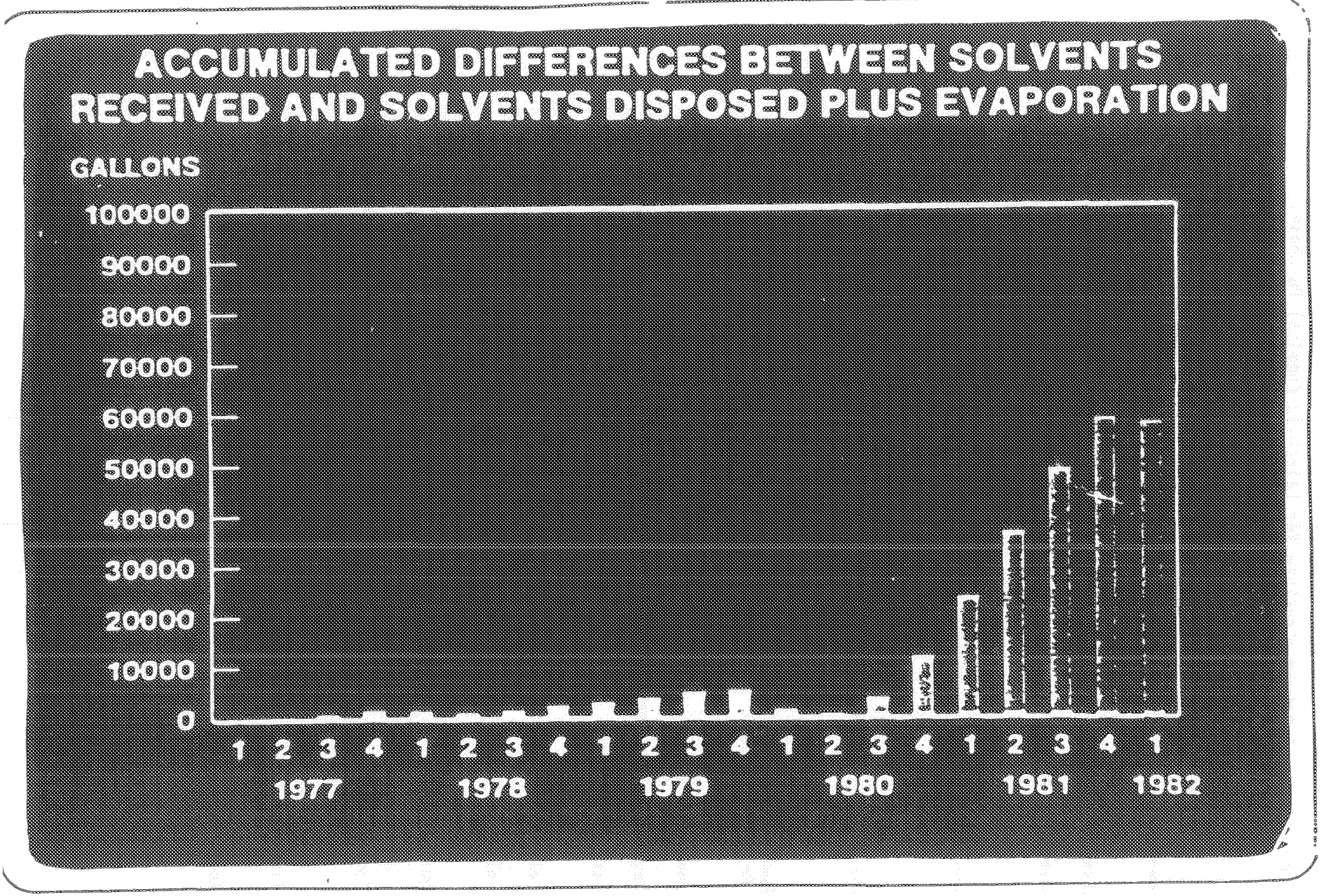
GRAPHS AND TABLES

<u>FAIRCHILD'S SOUTH SAN JOSE FACILITY</u>

<u>CHRONOLOGY OF OPERATIONS</u>

1977	(April) South San Jose Plant begins operation -- start-up phase. Only Wing A (one-half of present facility) facilitized.
1978	Full production commenced in Wing A.
1979	Further facilitization of plant to prepare for opening of Wing B. Chemical inventories built up late in year to prepare for expanded operations.
1980	(April) Expanded operation begins.
1981	Failure of large (bulk) solvent waste tank discovered in December; appropriate agencies notified, temporary solvent waste tank installed immediately, remediation program begun, materials balance study initiated.


RELATIONSHIP OF SOLVENT USAGE TO SOLVENT DISPOSAL
GALLONS
25000
20000
15000
10000
5000
KEY:
SOLVENT RECEIVED
EVAPORATION
DRUM DISPOSAL
BULK DISPOSAL
1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1
1977
1978
1979
1980
1981
1982


ACCUMULATED DIFFERENCES BETWEEN SOLVENTS RECEIVED AND SOLVENTS DISPOSED PLUS EVAPORATION
GALLONS
100000
90000
80000
70000
60000
50000
40000
30000
20000
10000
0
1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1
1977
1978
1979
1980
1981
1982

Appendix D.3

Appendix B. Database Structure for Fairchild Chemical Purchases

Identification Number -	Box and document number assigned to the document by Landels, Ripley and Diamond.
Chemical Company -	Name of the chemical vendor.
Bernal Road -	Entered to assure that the chemical was purchased for the Fairchild South San Jose facility on Bernal Road.
Document Type -	The type of document used to order chemicals. Most documents were purchase order releases. We had very few purchase requisitions and invoices.
Blanket P.O. Number -	The number of the blanket purchase order agreement from which the blanket purchase order releases were drawn.
Puchase Order Release Number -	The pre-printed number on the purchase order release document.
Invoice Number -	The number on invoice documents.
Requisition Number -	The number on purchase requisition documents.
Date Requested -	The date the purchase order release was requested.
Solvent Name -	The name of the solvent purchased.
Solvent Code -	The coded grouping in which DHS placed the solvent.
Quantity -	The number of units of solvent ordered and denoted as received.
Container -	The type of container the solvent was dispensed in. Most solvents were sold in one gallon\ bottles, five gallon pails, or 55 gallon drums.
Unit -	The unit of measure by which the solvent was sold.
Unit Cost -	Cost of the solvent per unit. We took this information to help us calculate the total solvents purchased.

Total Cost -	Total cost for the quantity of solvent purchased.
Total Gallons -	The total gallons of solvent purchased. This data was taken directly from the chemical purchase document or it was calculated by DHS.
Solvent Name, etc. to Total Gallons -	These data items are repeated for every solvent listed on a purchase document. There were as many as nine different solvents ordered on a single purchase document.
Requester Initials -	The initials of the Fairchild employee who made the chemical purchase request.
Date Received -	The date the chemicals were received.
Bill of Lading -	We entered a "Y" for yes if there was a bill of lading from the chemical vendor attached to the purchase order.
Illegible -	We entered a code to denote legibility problems.
Other Problems -	We entered a description of the type of problem.

Appendix C. Example of One of Fairchild's Completed Hazardous Waste Manifests

0520

REVERSE SIDE FOR INSTRUCTIONS. PLEASE TYPE OR PRINT CLEARLY. PRESS HARD

CALIFORNIA HAZARDOUS WASTE MANIFEST

STATE DEPARTMENT OF HEALTH SERVICES
HAZARDOUS MATERIALS MANAGEMENT SECTION
744 P STREET, SACRAMENTO, CA 95814

(1) MANIFEST NO. 088- 23533

GENERATOR (GENERATOR MUST COMPLETE)

(2) NAME Fairchild Semico Haven
EPA NO CAD097011218
ADDRESS 101 Bernal Rd PHONE NO 224-7116
STATE CITY ZIP San Jose, Ca 95119

(3) DESIGNATED TSD FACILITY AUTHORIZED TO OPERATE AS APPROVED STATE OR FEDERAL PROGRAM
NAME I.T. Corp. S.J. Transfer Facility
EPA NO CAD000633115
ADDRESS 2020 Tenner Rd PHONE NO
STATE CITY ZIP CA San Jose 95035

(4) ALTERNATE TSD FACILITY
NAME
EPA NO
ADDRESS PHONE NO
STATE CITY ZIP

U.S. DOT PROPER SHIPPING NAME
WASTE
WASTE Flammable Liquid | Flammable | UN1993 | 1039 | Gal

CONTAINER NO
TYPE: DRUMS / BAGS / CARTONS / TANK TRUCK / DUMP TRUCK / OTHER

(5) WASTE CATEGORY Solvent Mix
(7) EX HAZ WASTE PERMIT NO
(8) GENERATING PROCESS Electronic Mfg.

(9) LIST COMPONENTS (CONC. RANGE UPPER / LOWER)

	Component	Upper	Lower	
A	Xylene	1	1	% PPM
B	Acetone	1	1	% PPM
C	IPA	1	1	% PPM
D				% PPM
E				% PPM
F				% PPM
G				% PPM

NON HAZARDOUS MATERIAL Water 95 %

(10) WASTE PROPERTIES pH — TOXIC / FLAMMABLE / CORROSIVE/IRRITANT / REACTIVE / SENSITIZER / CARCINOGEN/MUTAGEN
(11) PHYSICAL STATE: SOLID / LIQUID / SLUDGE / SLURRY / GAS / OTHER
(12) SPECIAL HANDLING INSTRUCTIONS: GLOVES / GOGGLES / RESPIRATOR / OTHER

GENERATOR CERTIFICATION: This is to certify that the above named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and EPA.

IN THE EVENT OF A SPILL CONTACT THE NATIONAL RESPONSE CENTER U.S. COAST GUARD 800-424-8802

(13) [signature] 2/18/81
SIGNATURE OF AUTHORIZED AGENT — DATE

TRANSPORTER (HAULER MUST COMPLETE)

(14) NAME I.T. Trans
EPA NO CAD000633115
(15) PICK UP DATE 2-18-81 TIME 12:30 AM/PM
ADDRESS 2020 Tenner Rd CITY San Jose STATE CA ZIP 95035
PHONE NO 408 ... TRUCK # ...
(16) [signature] 2-18-81
SIGNATURE OF AUTHORIZED AGENT — DATE

TSD FACILITY (FACILITY OPERATOR MUST COMPLETE)

(17) NAME
EPA NO
(18) QUANTITY (IF MEASURED)
(19) STATE FEE (IF ANY)
PHONE NO
(20) INDICATE ANY SIGNIFICANT DISCREPANCIES BETWEEN MANIFEST AND SHIPMENT
(21) HANDLING OR DISPOSAL METHOD: SURFACE IMPOUNDMENT / LANDFILL / INJECTION WELL / LAND TREATMENT / TREATMENT (SPECIFY) / RECOVERY OR REUSE / STORAGE/TRANSFER
(22) IF WASTE IS HELD FOR DELIVERY ELSEWHERE SPECIFY THE DESIGNATED TSD FACILITY
NAME EPA NO
(23) SIGNATURE OF AUTHORIZED AGENT — TITLE — DATE ACCEPTED

EPA WASTE CODE

003010